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An Economic Research Service Report

Tracking Foodborne Pathogens from Farm to Table

Data Needs To Evaluate Control Options

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Abstract

Food safety policymakers and scientists came together at a conference in January 1995 to evaluate data available for analyzing control of foodborne microbial pathogens. This proceedings starts with data regarding human illnesses associated with foodborne pathogens and moves backwards in the food chain to examine pathogen data in the processing sector and at the farm level. Of special concern is the inability to link pathogen data throughout the food chain. Analytical tools to evaluate the impact of changing production and consumption practices on foodborne disease risks and their economic consequences are presented. The available data are examined to see how well they meet current analytical needs to support policy analysis. The policymaker roundtable highlights the tradeoffs involved in funding databases, the economic evaluation of USDA's Hazard Analysis Critical Control Point (HACCP) proposal and other food safety policy issues, and the necessity of a multidisciplinary approach toward improving food safety databases.

Note: Opinions expressed in this proceedings are those of the authors; they do not necessarily reflect policies or opinions of the U.S. Department of Agriculture.

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Section I

Introduction

Tracking Foodborne Pathogens from Farm to Table: Data Needs To Evaluate Control Options

Julie A. Caswell
University of Massachusetts at Amherst

Better information on the incidence and costs of foodborne illness has been accumulated through careful research over the last decade. Based on this research, our best estimates are that foodborne pathogens account for between 6 and 33 million cases of foodborne illness per year. The very broad range of this estimate is suggestive of how limited our knowledge is of the importance of foodborne pathogens in the food supply. The estimated range of deaths related to foodborne pathogens, from 525 to 9,000 cases per year (Council for Agricultural Science and Technology, 1994), is even broader. An estimate that the productivity losses from a few major pathogens range from $5 to $6 billion per year (USDA FSIS, 1995) gives an economic perspective to the impact of foodborne pathogens.

Researchers working in the area of foodborne pathogens and their impact on human health are constantly amazed at the limitations of our current information. Making these limits even more striking is the fact that new pathogen tests and improved epidemiological methods are making new, closer links between human disease and foodborne sources, thus expanding the universe of information to be known. How much more striking it is to the person on the street to find out that we do not know, for example, the incidence of many important foodborne illnesses and the specific major sources of related foodborne pathogens.

It is this context that led to the organization of the conference, "Tracking Foodborne Pathogens From Farm to Table: Data Needs to Evaluate Control Options," and which makes these proceedings particularly important. Better data and knowledge are needed as a preliminary step toward evaluating and eventually adopting more effective ways of controlling foodborne pathogens. The multidisciplinary approach reflected in this conference is critical to addressing the complex issues involved in foodborne illness for two reasons. First, the sources of foodborne illness due to pathogens need to be understood at the farm level, processing level, and level of final consumption. A range of natural, biomedical, and social

scientists can contribute to this understanding. The picture is likely to be limited without a rounded perspective on sources, costs, and consequences.

Second, we simply cannot afford, from a financial point of view or in terms of commitment of scientists' time, to collect and analyze single-purpose databases on foodborne pathogens and related illness. Multidisciplinary teams have the best potential to make every effort yield the maximum return in new knowledge and better understanding. Their work also has the best potential to yield insights that will be useful in answering the key questions facing program agencies that are responsible for assuring the food supply's safety and companies that are committed to producing high-quality products. The cooperation between university, Government, and industry scientists and officials that is evident in this conference is an excellent basis for pushing out the frontiers of our ability to track foodborne pathogens from the farm to the table and for design of effective control options.

The conference represented by these proceedings is one of a series organized by members of Regional Research Project NE–165 under the title, "Private Strategies, Public Policies, and Food System Performance." NE–165 is a group of more than 70 economists at landgrant universities and Government agencies conducting research on the food system. NE–165 has organized these conferences as a means of building, brick-by-brick, the knowledge base necessary to understand the economics of food safety and nutrition generally; companies' strategic choices in providing safety and nutrition; and Government's activities to assure the quality of the food supply. The first conference in 1991 on the "Economics of Food Safety" was followed in 1993 by a conference on methodologies for "Valuing Food Safety and Nutrition." The latest conference, "Tracking Foodborne Pathogens from Farm to Table: Data Needs to Evaluate Control Options," addresses the underlying need for better data to evaluate the scope and importance of foodborne-pathogen risks to human health. This conference represents an impressive effort by many researchers from several disciplines to

work together to build a complete three-dimensional picture of foodborne pathogens and their ultimate impact on human health.

Excellent leadership in organizing this conference was provided by the team of Tanya Roberts, U.S. Department of Agriculture (USDA) Economic Research Service (ERS); Helen Jensen, Department of Economics, Iowa State University; and Laurian Unnevehr, ERS. Thanks are also due to Shannon Reid Hamm, ERS, for coordinating the logistical details. Cosponsors included the ERS; USDA Food Safety and Inspection Service; USDA

Animal and Plant Health Inspection Service; Farm Foundation; Food Safety Consortium; U.S. Department of Health and Human Services Centers for Disease Control and Prevention; American Veterinary Medical Association; Food Marketing Policy Center, University of Connecticut; and Center for Agricultural and Rural Development, Iowa State University. Associate cosponsors were the International Meat and Poultry Hazard Analysis and Critical Control Point Alliance, and the National Foundation for Infectious Diseases. We sincerely thank the organizers, sponsors, and cosponsors for their contributions.

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Council for Agricultural Science and Technology. 1994. *Foodborne Pathogens: Risks and Consequences.* Task Force Report No. 122. Sept.

U.S. Department of Agriculture, Food Safety and Inspection Service (USDA FSIS). 1995. "Pathogen Reduction; Hazard Analysis and Critical Control Point (HAACP) Systems; Proposed Rule," *Federal Register*, Vol. 60, No. 23, Feb. 3, pp. 6773–6889.

Errata sheet

Tracking Foodborne Pathogens from Farm to Table: Data Needs to Evaluate Control Options

Please replace the second paragraph in "Data on Foodborne Disease Cases, Severity, and Costs" by Jean C. Buzby (page 3) with the following:

How important are foodborne diseases? In the United States, there are an estimated 6.5 million to 33 million cases of foodborne disease each year, resulting in up to 9,000 deaths (CAST, 1994). ERS estimates U.S. medical costs and productivity losses for seven foodborne pathogens at $5.6 billion to $9.4 billion annually (Buzby and Roberts, 1995).

Buzby, Jean C. and Tanya Roberts. "ERS Estimates U.S. Foodborne Disease Costs." FoodReview Yearbook, U.S. Dept. of Agr., Econ. Res. Serv., Vol. 18, Issue 2, May-Aug., 1995.

Data on Foodborne Disease Cases, Severity, and Costs[1]

Jean C. Buzby
University of Kentucky

Emerging Food Safety Concerns

In the past in the United States, foodborne pathogens were a common source of illness due to poor sanitation and inadequate refrigeration and canning practices, and because diseased animals were killed under unsanitary conditions. Although food preparation and storage conditions have improved, new food safety concerns have arisen. Emerging pathogens, changes in production and distribution, and changes in the overall makeup of the population have contributed a new set of problems. After causing acute illness, many foodborne pathogens result in serious sequelae: miscarriages following listeriosis; hemolytic uremic syndrome from *Escherichia coli* O157:H7 infections; reactive arthritis following *Salmonella*, *Shigella*, and *Yersinia* infections; and Guillain-Barré syndrome (GBS) associated with *Campylobacter jejuni* infections (Kaldor and Speed, 1984; Griffin et al., 1988).

How important are foodborne diseases? In the United States, there are an estimated 6.5 million to 81 million cases of foodborne disease each year, resulting in 525 to 9,000 deaths and the loss of $8 million to $23 million in medical costs and lost productivity (Amler and Dull, 1987; Archer and Kvenberg, 1985; Todd, 1989; Garthright et al., 1988). New food safety concerns may raise the number of future cases.

New and Emerging Pathogens

In the last 10 to 20 years, several important foodborne organisms have been recognized as human pathogens, including *E. coli* O157:H7, *Vibrio vulnificus*, and *Campylobacter*. *E. coli* O157:H7 was recognized as a cause of human illness following two outbreaks of bloody diarrhea in 1982, and it has since emerged as an important cause of both bloody and nonbloody diarrhea (Griffin, 1995). Most cases of the hemolytic uremic syndrome, the major cause of kidney failure in children, are now known to be caused by infection with *E. coli* O157:H7. *V. vulnificus,* another newly recognized pathogen, causes sepsis and death among persons with liver disease. *Campylobacter*, a previously unknown pathogen, is now identified as the most common cause of

bacterial gastroenteritis in the United States, exceeding *Salmonella* in frequency. In addition to new pathogens, new modes of transmission for known pathogens have recently been identified. Since the 1980's, *Salmonella enteritidis* has emerged as a major public health concern because of transmission of the organism through intact shell eggs. In 1976, 5 percent of *Salmonella* isolates that were reported to the Centers for Disease Control and Prevention (CDC) were *S. enteritidis*; the number increased to 26 percent in 1994, and *S. enteritidis* is now the most common *Salmonella* serotype reported in the United States (CDC, unpublished data). *V. cholerae* O1, previously thought to be a waterborne pathogen, and *Listeria*, for which transmission routes were unknown, have recently been recognized as foodborne pathogens (St. Louis et al., 1990; Schlech et al., 1983).

Changes in the Food Industry

Large producers who employ centralized production methods may increase the risk of large outbreaks over broad geographic areas. In 1993, more than 700 reported cases and 4 deaths were attributed to a multistate outbreak of *E. coli* O157:H7 infections in the Western United States when contaminated hamburger patties were distributed by a national fast food chain (Griffin, 1995). Rapid interstate and international distribution of perishable foods may also lead to outbreaks of illness; outbreaks may occur even when levels of food contamination are low, and contamination may be difficult to detect and trace. In 1990, 295 isolates of *S. chester* were reported in 28 States. Cantaloupe were implicated, especially those eaten at salad bars, and their origins were traced to Mexico and Central America (Ries et al., 1990). In 1991, 400 isolates of *S. poona* were

reported in 23 States and Canada. Again, cantaloupe in fruit salads or salad bars were implicated, and their origins were traced to the Rio Grande region of Texas (USDHHS CDC, 1991). Tomatoes shipped from South Carolina packing houses were linked to a four-State outbreak of *S. javiana* in 1990, and to a three-State outbreak of *S. montevideo* in 1993 (Hedberg et al., 1994). In each of these outbreaks, only a few cases occurred in each locale, making detection difficult.

New products and processes may also increase the risk of foodborne illness. Hazelnut yogurt produced with a sugar substitute was the source for a large outbreak of botulism in the United Kingdom. Changing one of the ingredients from sugar to a sugar substitute altered the water activity of the product sufficiently so that spores of *C. botulinum* (inhibited by the water activity in the original product) were able to germinate and produce toxin (Critchley et al., 1989). A previously safe product became dangerous due to changes in the manufacturing process. Several outbreaks of botulism have been caused by salsa made with a new variety of low-acid tomatoes. The tomatoes, desired by consumers for their sweetness, were made into salsa with a higher pH than salsa made with other tomatoes. The product had been safe because it was acidic enough to prevent botulism spores from germinating; but the increased pH of the salsa could not prevent growth of the spores.

Changing Populations

As populations change, new concerns arise about food safety. In the United States, the number of elderly and immunocompromised persons (those with acquired immune deficiency syndrome (AIDS), organ transplant patients, and so on) is rising. These persons are more susceptible to opportunistic and low-dose pathogens, and more likely to develop secondary sequelae. Salmonellosis is 20 times more common in AIDS patients than in those without AIDS (Angulo and Swerdlow, 1995). *Campylobacter* and *Shigella* infections have also increased in this population. Foodborne infections in immuno-compromised patients are also more likely to be followed by complications such as sepsis and meningitis. Recurrent salmonella bacteremia has become a common problem in patients with AIDS (Angulo and Swerdlow, 1995).

Ethnic populations may follow food practices that put them at risk of foodborne illness. The consumption of raw limpets by the Portuguese population has been responsible for cases of typhoid fever and Norwalk-like gastroenteritis in New England, California, and Canada (Townes et al., 1994). In the general population, changes in eating styles may also raise the risk of foodborne illness, particularly increased consumption of fast food: several outbreaks of *E. coli* O157:H7 infections,

including the first outbreak in 1982 and the large one in the Western United States in 1993, were associated with hamburgers from fast-food chains (Griffin, 1995). Salad bars have been implicated in several outbreaks of *Salmonella* and *E. coli* O157:H7 infections, perhaps because pathogens on the surfaces of fruits are inoculated during slicing from the peel into the fruit itself. If these slices are not kept at sufficiently cold temperatures, the organism may multiply (Hedberg et al., 1994).

The emergence of new pathogens and modes of trans-mission make it essential to maintain and improve foodborne illness data, particularly the reporting and tracking of pathogens. *E. coli* O157:H7 is a case in point. In 1987, only 2 States, Minnesota and Washington, were routinely reporting cases; 11 States were reporting cases by 1992, 18 by 1993, and 26 by August 1994. By January 1995, 6 additional States had agreed to report cases, and 16 States were considering adding *E. coli* O157:H7 infections to the list of notifiable diseases. Currently, only two States—Arkansas and Wyoming—have no plans to report cases of foodborne illness. Because low-dose pathogens, such as those associated with fresh produce, may cause outbreaks that are widely dispersed and difficult to detect, adequate and rapid reporting of cases is necessary to identify outbreaks and implement effective control measures in a timely manner.

Food safety data should be regularly collected to track the changing impact of foodborne pathogens in the growing elderly and immunocompromised populations.

Data on Foodborne Disease

As new food safety concerns arise, comprehensive data are required to obtain a complete picture of foodborne disease—its incidence, severity, and economic burden. A variety of entities collect information and data useful for estimating the costs of foodborne illness, including the following Federal agencies:

- CDC, including the National Center for Health Statistics (NCHS)

- Health Care Financing Administration (HCFA)

- U.S. Bureau of the Census

State health departments also routinely collect informa-tion on foodborne illness, some of which is not available from Federal sources. Information is also available from similar national or local agencies in other countries, and from the United Nations and the World Health Organization (WHO) for member countries.

The fastest growing sources of information on the cost of foodborne illness are in the private sector: health management organizations (HMO's) and insurance companies have emerged as valuable sources of information on comprehensive treatment costs and disease severity distributions.

Currently, the most accessible data available to researchers come from the national surveys administered by the NCHS. This paper reviews the characteristics of the five national surveys administered by NCHS and of the vital statistics it collects. As more sources of health information become available, accurate estimates of the cost of foodborne illness will rely on synthesis of information from various sources, each with different strengths and limitations.

Description of National Health Surveys

The NCHS (part of the CDC's Public Health Service) administers six data sources of information relevant to food safety research: (1) the National Hospital Discharge Survey, 1965–1992; (2) the National Mortality Follow-back Survey, 1986; (3) the National Ambulatory Medical Care Survey, 1973–1991 (assorted years); (4) the National Medical Care Utilization and Expenditure Survey, 1980; (5) the National Health Interview Survey, 1957–1993; and (6) Vital Statistics.

Pathogens are identified in the surveys by International Classification of Diseases (ICD) codes (8th or 9th revision, depending on survey year—typically, ICDA–8 codes are used for data compiled through 1978 (USDHHS, 1979), and ICD–9–CM codes for data from later years (USDHHS, 1980)). These codes link the surveys and help maintain consistency across samples. The usefulness of these databases for studying foodborne illness is determined largely by the assignment and use of ICD codes.

Identification of pathogens does not indicate percentage of foodborne disease. A few foodborne illnesses, such as *E. coli* O157:H7 infections, do not have assigned ICD codes. More importantly, the extensive use of generic categories (such as unspecified gastroenteritis) complicates the determination of the extent of foodborne illness in the United States, because even causative pathogens are not identified.

Cases of illness obtained using ICD codes represent all types of transmission (including foodborne, waterborne, and person-to-person). Because ICD codes do not distinguish among sources of contamination, it is necessary to find, for a particular illness, the best estimate (or low and high estimates) of the percentage of cases caused by foodborne pathogens, and to multiply

this percentage by the number of all cases to get the total number of foodborne cases. This caveat applies to all databases that use ICD codes.

National Hospital Discharge Survey

The National Hospital Discharge Survey (NHDS) is the main source of detailed information on patients discharged from short-stay hospitals in the United States.[2] The NCHS has conducted this survey each year since 1965. The survey samples about 1 percent (roughly 400–500) of all short-stay hospitals in the 50 States and the District of Columbia, excluding all military, Federal, and Veterans Administration hospitals. The unit of observation is a hospital discharge. The NHDS data from 1970–92 are available to the public, with a total of 180,982 to 274,311 medical records per year.

The NHDS provides estimates of hospital use for diseases with ICD codes. In addition to collecting the standard demographic variables (including age, race, sex, and marital status) for the patients discharged, the NHDS provides information on admissions (including admission and discharge dates), diagnoses, procedures performed, and expected source of payment (table 1). Depending on the survey year, the data provide information on up to seven diagnoses and up to four procedures (such as surgical procedures and artificial ventilation) for each discharge. The first diagnosis represents the primary illness or the reason for admission.

Sample design. The sample design for the NHDS was a two-stage process for the years 1965–77, and was changed to a different design for the years 1988–90. The two-stage process consisted of identifying a sample of U.S. hospitals and then sampling discharges within hospitals selected. Hospitals were selected from a pool of 6,965 short-stay hospitals listed in the 1963 National Master Facility Inventory of Hospitals (MFI), and from newer hospitals sampled in various years for inclusion (Moss and Moien, 1987, p. 11). All larger hospitals considered (with 1,000 beds or more) were automatically included in the NHDS sample. Remaining hospitals were divided into 24 size-by-region classes, and hospitals were drawn from these classes using probabilities that favored selection of the larger ones (Moss and Moien, 1987, p. 11). For each hospital sampled, a procedure was implemented that selected a systematic random sample from a daily list of all inpatients discharged, and then abstracted data from medical records (Rice et al., 1989).

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[2]Short-stay hospitals used in the survey are those with at least six hospital beds staffed for inpatient use, and where average length of stay for each patient is less than 30 days (NCHS, 1987, p. 12).

Table 1—Summary of National Hospital Discharge Survey data

Information type	Information/entry
Patient data	Age at date of admission Sex Race Marital status Expected source of payment—primary and others (1977–92, 10 categories) Date of admission (month, day, year) Date of discharge (month, day, year) Discharge status
Diagnostic codes	1970–78: one to five 4-digit ICDA–8 codes 1979–92: one to seven 5-digit ICD–9–CM codes
Diagnosis-related group codes	1986–92
Procedure codes	1970–78: zero to three 3-digit ICDA–8 codes 1979–92: zero to four 4-digit ICD–9–CM codes
Dates of procedure[1]	1979–92, one to four; month, day, year
Hospital data	Bed size of hospital Ownership of hospital Length of stay in days Weight (final adjusted for each sample record) Geographic location

Note: Years available to public are 1970–92 (although the survey has been conducted since 1965). Data can be purchased from the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161 (703-487-4650)) and the Government Printing Office (202–512–1530).
[1]If procedure code is not zero.
Source: NCHS, 1994, p. 48.

After 1988, the pool of hospitals was no longer based on MFI hospitals, but rather on hospitals in the SMG Hospital Market Database (updated about every 3 years). All hospitals in this new pool with 40,000 discharges or more, or with 1,000 beds or more annually, were automatically included in the NHDS sample, and discharges were randomly selected for study. Remaining hospitals in the NHDS sample were obtained through a stratified three-stage design, which (1) determined regions of the United States (or primary sampling units (PSU's)); (2) chose hospitals within the PSU's; and (3) selected a sample of discharges from each hospital using systematic random sampling techniques.

Prior to 1985, all data collection and information transcription were done manually. Since 1985, the NHDS has used manual sample selection/data abstraction and automated data tapes purchased from individual hospitals, commercial abstracting services, and State data systems. Data tapes are coded, weighted, and edited using NCHS procedures, such as adjusting for nonresponse, inflating estimates by the reciprocals of the sample selection probabilities, and implementing a ratio adjustment to fixed

totals (Moss and Moien, 1987, p. 11). One caveat in using NHDS data is that changes in design, data collection, and ICD codes over time may affect trend data.

Strengths and limitations of NHDS data. Although there is no coding specifically for "foodborne illness," the NHDS data are useful for tracking hospitalizations from specific foodborne illnesses caused by pathogens with ICD codes.[3] For foodborne diseases with assigned codes (such as botulism and salmonellosis), the NHDS can identify hospital patients diagnosed with the foodborne illness, and these estimates may be extrapolated to obtain lower bound estimates of incidence and prevalence in the United States. These estimates under-report foodborne illness cases, because not all illnesses result in hospitalization. Because the number of patients with foodborne illness in the data set is so low, incidence and prevalence should only be estimated for the most common conditions; the data should not be used to estimate mortality rates.

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[3]Therefore, no "foodborne illness" variable was extrapolated to the U.S. population.

Some patients with foodborne illnesses develop chronic sequelae, such as GBS, which may have their own ICD codes. However, the NHDS data for these sequelae do not indicate percentage of foodborne cases (for example, percentage of GBS induced by foodborne *C. jejuni*). Also, due to small sample size, estimates of relatively rare events are inaccurate (Kozak, 1994), which is important for food safety research because several foodborne illnesses, such as *V. vulnificus* infections, occur infrequently but have severe outcomes.

The NHDS provides some information on the severity and mortality of foodborne illness, to the extent that these variables can be observed during the hospital stay. However, some sequelae to foodborne illness can linger well beyond. For example, *C. jejuni* infections may lead to arthritis and GBS (typified by permanent paralysis or partial paralysis of uncertain duration). Additionally, the NHDS does not record cases of foodborne illness that resulted in death before hospitalization or after discharge from the hospital. Therefore, NHDS estimates of death from foodborne illness are underestimates. Death certificates may be a better source of data on mortality attributable to foodborne illness.

The NHDS does not provide direct medical and non-medical cost information. However, indirect costs can be calculated using the survey data on number of days hospitalized and age at death. Number of days hospitalized underestimates the number of days lost from work, because almost all patients spend additional time recuperating at home. To estimate costs of lost productivity, extrapolation from the number of days hospitalized to the number of days lost from work is therefore necessary.

One strength of the NHDS data is that they draw on hospital records, which are less prone to underreporting and are usually accepted as more accurate than patient interview data (which rely on patient recall) (Moss and Moien, 1987, p. 2). The NHDS data also report inpatient data for those who stay in the hospital less than 1 day (Moss and Moien, 1987, p. 2), although there are often problems with what is recorded as the cause of admission.

One limitation of the NHDS and other surveys that use ICD codes is that the data do not indicate whether the illness was transmitted by food or by some other means (such as water).[4] Thus, case estimates for a pathogen-related foodborne illness must be derived by multiplying the total number of cases by the probability (found in the

literature) that the infection had food origins. This product can be extrapolated to the U.S. population to estimate the annual number of cases of foodborne illness. The NHDS cannot provide information on the average frequency per year that an individual has foodborne illnesses.

For the NHDS and other surveys that use ICD coding, another limitation is that it is unclear how often foodborne illness falls into residual "other" or "unspecified" categories. The residual category can offer little help in determining the incidence or prevalence of foodborne disease. For example, NHDS data may state that a patient had an "unspecified gastroenteritis and colitis" rather than a specific foodborne illness, either because no laboratory tests were performed to isolate the pathogen, or because there was no ICD code for the diagnosed pathogen.

There may be a lag between the time when a diarrheal illness is first identified as significant, and the time when an ICD code is assigned. This lag time poses problems in documenting a historical series on the incidence and/or prevalence of the diarrheal illness.

The NHDS includes admissions from nursing homes and patients who die in hospitals (Moss and Moien, 1987, p. 2), but does not record patients with foodborne disease while in nursing homes. These illnesses may be recorded in the National Nursing Home Survey administered by the NCHS. The NHDS does not include military and other Federal hospitals.

National Mortality Followback Survey

The 1986 National Mortality Followback Survey (NMFS) is also administered by the NCHS in collaboration with nine cosponsoring Federal agencies. The unit of observation is a death, and, as with most NCHS databases, the Bureau of the Census was the data collection agency. The data provide a nationally representative sample (roughly 1 percent) of persons aged 25 years and older who died in 1986 in the United States, including the District of Columbia but excluding Oregon.

Table 2 presents the variables in the NMFS. In general, variables include: (1) health care provided in the last year of life; (2) mortality and socioeconomic status; and (3) associations between mortality and risk factors (NCHS, 1990a).

Sample design. The NMFS data supplemented information from death certificates in the vital statistics file with three types of linked records: (1) a 24-page followback informant questionnaire (completed by the child, spouse, and/or other next of kin identified on the death certificate); (2) a facility abstract record; and (3) a

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[4]Steahr (1995) develops two lists of pathogens and their associated ICD codes. The first presents codes for illnesses that are predominately either foodborne or waterborne. The second has "codes composed of a mixture of foodborne and non-foodborne pathogens."

16-page hospital, hospice, or nursing home questionnaire. Use of the latter two data categories depended upon whether the patient received services from hospitals or institutions during the last year of life. The four data sources have been cross-checked for consistency, thereby increasing data reliability.

The NMFS sample of death certificates was obtained from the 1986 sample of 18,733 decedents in NCHS's Current Mortality Sample (CMS) (NCHS, 1990a). The CMS contains 10 percent of the death certificates from each State that are sent to NCHS roughly 3 months after death.

Table 2—Summary of National Mortality Followback Survey, by type of record

Death certificate	Informant questionnaire	Facility abstract record (similar to hospital discharge summary)	Staff person questionnaire (nursing home, hospice)
Race	Race		Race
Sex	Sex		Sex
Age (in years)	Age (in years)		Age
Birth date	Birth date		
Education level	Education of decedent and spouse		Education of decedent
	Total family income		
Date of death	Date of death		
Place of death	Inventory of all facilities used in last year of life		Inventory of all facilities used in last year of life
	Time in facility	Discharge/admission dates	Time in facility
		Diagnoses (ICDA–8, ICD–9–CM)	
		Principal/other surgical and diagnostic procedures (ICDA–8, ICD–9–CM)	
		Type of facility	
		Other facility used	Other facility used
		Names/addresses of facilities	Names/addresses of facility
Birthplace			
	Medical history (e.g., cancer, heart, lung, cerebrovascular, disease, gynecological history)		Medical history (e.g., cancer, heart, lung, cerebrovascular disease, gynecological history)
	Medical care (in last year)		Medical care (in last year)
	Problems getting care		
	Activities in daily living		Activities in daily living
	Costs of care		Costs of care
	Sources of payment for care		Sources of payment for care
	Out-of-pocket cost		
	Main source of payment		Main source of payment
	Life style and health		Health
	Social support (provider, type)		
Usual occupation	Kind of work done longest		Kind of work done longest
Type of business/ industry	Number of years doing work		Number of years doing work
	Activity on job		Activity on job
	Spouse's occupational history		
Veteran status			Veteran status
Marital status	Marital status at death		Marital status at death
	Marriage length		Marriage length
	Number of spouses (ever had)		
	Family medical history (e.g., heart disease)		
	Informant's relationship to decedent		
	Time informant lived with decedent		

Note: Year available is 1986. Data can be purchased through the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161 (703–487–4650)) or Government Printing Office (202–512–1530).
Source: NCHS, 1994, p. 23.

Next of kin identified on death certificates were asked to complete followback informant questionnaires.

The NMFS data underwent a three-stage cleaning and weighting process: (1) issues on the probability of selection were addressed; (2) nonresponses were adjusted for data from each State; and (3) poststratification to a national sample was completed (Spitler, 1994). Additionally, a consistency edit check was performed.

Information relevant to food safety research may be found in three areas of the NMFS: (1) the underlying cause of death; (2) multiple causes of death; and (3) facility information as a clinical modification. The NMFS data captured only out-of-pocket expenses, and did not attribute direct medical and nonmedical costs to specific illnesses. However, the NMFS did provide age at death, which can be used to estimate costs of lost future productivity due to premature mortality.

Strengths and limitations of NMFS data. One strength of the NMFS data is that they are more comprehensive than data from death certificates because they include death certificate data plus data from a followback questionnaire, facility abstracts, and a hospital, hospice, or nursing home questionnaire. The NMFS data may also identify the underlying etiology and disease-related factors.

However, the usefulness of NMFS data for research on foodborne illness is limited. First, the data are old. Second, as with the NHDS, the NMFS is helpful in identifying the incidence or prevalence of foodborne illness only to the extent that the data contain ICD codes for the pathogen(s) of interest. In the NMFS, most foodborne disease cases are coded under general categories, such as 008, 009, and 558.9, instead of under the name of a causative microorganism (Council for Agricultural Science and Technology, 1994). Smith and Blaser (1985) report that in Colorado, all deaths linked to diarrhea are automatically coded as "noninfective diarrhea" unless the term "infective" appears on the death certificate. And even when a causative microorganism is implicated, the NMFS data do not identify the percentage of illnesses attributed to food.

Additionally, the data most likely underestimate the frequency of foodborne illness because patients may conceivably contract more than one illness in the last year of life. Illness associated with foodborne pathogens is usually not recorded. The data provide only limited information on the medical history of the deceased. Therefore, it is usually impossible to develop a good case definition of mortality associated with foodborne pathogens.

Another limitation is that nonresponses associated with facility data were not taken into account (Spitler, 1994).

For example, a patient may have been treated at more than five facilities in the year prior to death, but only five provided NCHS with information.

National Ambulatory Medical Care Survey

Another continuing national survey administered by the NCHS is the National Ambulatory Medical Care Survey (NAMCS). The NAMCS provides a representative sample of all U.S. ambulatory office visits and calls to a physician where patients are seen in an office setting by, or have contact with, doctors of osteopathy and medical doctors other than physicians in Government service and pathologists, anesthesiologists, and radiologists. The survey includes only physicians classified by the American Osteopathic Association or the American Medical Association as providing "office-based patient care" (Steahr, 1995). The domain of the survey is randomly chosen regions or counties in the conterminous United States, and the unit of observation is an office visit.

The NAMCS data include treatment prescribed, final disposition of the visit, and whether the patient had previously been seen by the physician (table 3). The patient's verbatim description of the principal reason for the visit and/or of the problem to be treated is collected, along with the physician's principal diagnosis. As with the NHDS data, ICDA–8 codes are used for data up through 1978, and ICD–9–CM codes for later years. The NAMCS data are available for individual years (1973, 1975–81, 1985, and 1989–91); number of records per year ranges from 29,102 to 71,594 (less than 1 percent of all physician visits per year).

Sample design. The NAMCS uses a multistage probability sample design that involves: (1) identifying PSU's, such as counties and townships; (2) identifying and sampling physician practices within these PSU's; and (3) identifying a systematic random sample of patient visits within the selected physician practices (Schappert, 1994, p. 17). Physicians selected for the survey are randomly assigned a 7-day reporting period, during which they maintain a list of all patients who visit or call their offices. Prior to the designated week, trained interviewers provide survey materials and instruct the physicians and their staff in methods and definitions to be used in the survey. An encounter form is given to physicians and their staff for recording data from the sample of patient visits.

The NAMCS data are organized by office visit. Records are tabulated and the sample is weighted to adjust it to the U.S. population. Estimates are typically adjusted for nonresponse.

As with the other NCHS surveys, the NAMCS data cannot be used to determine how many times, on average, a

Table 3—Summary National Ambulatory Medical Care Survey data

Information type	Information/entry
Patient data	Date of visit
	Date of birth
	Sex
	Race (revised in 1979)
	Ethnicity (1979 to present)
	Expected source(s) of payment (1985 to present)
	Was patient referred by another physician? (1977 to present)
	Patient's reason(s) for visit (up to three) (classification revised in 1977)
	Physician's diagnosis(es) (up to three) (ICD–9–CM used from 1979 to present)
	Has the physician seen patient before?
	If yes, was it for the same condition?
	Diagnostic/screening services[1]
	Counseling/advice[1]
	Selected types of therapy[1]
	Medications (drugs) provided (up to five) (from 1980 to present)
	Is medication new? (1985 to present)
	Disposition of visit
	Duration of visit (in selected time intervals)
	Patient weight (an inflation factor assigned to the visit)
	Geographic region
	Standard metropolitan statistical area (SMSA) or non-SMSA code
	Seriousness of the problem (1973–78 only)
	Time since onset of complaint (1977–78 only)
	Major reason for visit (1973–76, 1979–81)
	Accidental injury or product-related illness (1979 only)
	Is this visit injury related (1991–92)
	Glucose tests (1985 only)
	Does patient smoke cigarettes? (1991–92)
	Ambulatory surgical procedures (if any) (1991–92)
	Does patient now have:
	Depression? (1991–92)
	Hypertension? (1991–92)
	Hypercholesterolemia? (1991–92)
	Obesity? (1991–92)
	Physician–patient linking code (from 1991)
Physician data	Specialty
	Type of doctor (medicine or osteopathy)
	Type of practice (sole, partnership, or group) (1973–85)

Note: Years available to public are 1973, 1975–81, 1985, 1989–92. To purchase 1973–1991 data, contact the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161, (703) 487–4650) or Government Printing Office (202–512–1530). For 1992 data, contact NCHS (301–436–7132).
[1]Updated and/or reformatted periodically in order to keep pace with the current spectrum of physician services being provided.
Source: NCHS, 1994, p. 48.

person gets a foodborne illness in a year, although one can link individual patients with foodborne illness to demographic characteristics.

Strengths and limitations of NAMCS data. One strength of the NAMCS is that it is one of the best sources of ambulatory care data for patients of all ages in the United States. When sufficient diagnoses are made, the NAMCS may provide information on foodborne illnesses with ICD codes. However, Helmick et al. (1994, p. 86)

report that in the NAMCS, 76 percent of infectious diarrheas are coded as "ill-defined." They attribute this to the rare occurrence of specific diagnoses for infectious diarrheas. In part, this is because laboratory confirmation of diagnosis by specific pathogen is unavailable at the time the survey form is filled out. Also, the NAMCS data are not appropriate for foodborne illnesses with low incidence rates. For example, none of the patients in the 1990 NAMCS were diagnosed with GBS (which may be precipitated by *C. jejuni* infections), whereas a 4-year

average (1987–90) of the NHDS estimated 7,874 cases of GBS annually.[5]

There were several changes in the sample design of the 1992 NAMCS, some of which resulted in an under-sampling (relative to previous years) of general and family practitioners (Schappert, 1994, p. 17). This may be an important consideration for food safety researchers, because patients with foodborne illness are most likely to see these types of practitioners. Also, caution should be used when disaggregating the 1992 NAMCS data by race, because black patients were more likely than nonblack patients to visit general and family practitioners.

National Medical Care Utilization and Expenditure Survey

The 1980 National Medical Care Utilization and Expend-iture Survey (NMCUES) was a panel survey cosponsored by the HCFA and NCHS. Between February 1980 and April 1981, the survey collected data on 6,798 families (17,123 people) in the U.S. civilian noninstitutionalized population (less than 0.1 percent of all families and people in the United States). Data covered areas such as general health, health insurance coverage, and associated charges and payment sources. The primary unit of observation was a household.

Sample design. The HCFA and NCHS contracted with the Research Triangle Institute (RTI) to collect data for the NMCUES, and RTI subcontracted with the National Opinion Research Center (NORC) and Systemetrics Inc. (Harlan et al., 1986). The sample for the NMCUES was taken from two independently drawn national subsamples of approximately the same size, one provided by NORC and the other by RTI. Both subsamples were from stratified, multistage area probability designs. Harlan et al. (1986) provide specifics on sample design.

The NMCUES had three main components. The first was the National Household Component. During a 14-month period in 1980–81, 6,798 households (17,123 people) participated in a series of five interviews separated by roughly 3-month intervals. The first, second, and fifth interviews were in person; the third and fourth surveys were conducted by telephone.

The second component was the State Medicaid Household Component. In 1980–81, 4,800 households (11,600 people) participated in California, Michigan, New York, and Texas. Each household was interviewed five times.

The third component was the Administrative Records Component. Information was gathered on medical care

payments for persons receiving Medicaid and Medicare, and on program eligibility. Reliance on Medicaid and Medicare data may cause bias if persons under these health plans differ from the population as a whole.

The NMCUES Public Use Data are available in seven fixed-length files, each representing a distinct category: person, family, medical visit, dental visit, hospital stay, medicines, and condition (table 4).[6] In the person file, there is one record for each person; the medical, dental, and hospital visit files have one record for each visit (discharged in 1980). The number of records per person in the medicine and condition files depends on the individual. In the medical visit file, for cases of foodborne illnesses with assigned codes, data are recorded on the type of physician, services provided, procedures performed, and condition associated with visits to emergency rooms, hospital outpatient departments, and providers' offices.

The medical condition file documents cases where a medical condition limited a person's activities (such as causing missed work days), or led the person to seek medical care. Each condition record includes the ICD code for the condition, the date of illness onset, prescribed medicines and other medical expenses, associated charges, numbers of visit types, and, where applicable, the reason(s) for not visiting a physician. Therefore, to some extent, the medical condition file captures more of the relatively less severe foodborne illness cases than does the medical visit file.

For analysis, sample weights were assigned to the NMCUES data to compensate for unequal probabilities of selection, and to adjust for total nonresponse and for portions of the population that the survey did not cover (Harlan et al., 1986, p. 43). Data imputation was also used for the NMCUES data analysis to compensate for item nonresponse and attrition.

Unlike many other national databases that focus on human illness and the utilization of medical care, the primary emphasis of the NMCUES is on expenditures and insur-ance (Garthright et al., 1988). The NMCUES provides data on medical charges and sources of payment, as well as some information on the indirect costs of foodborne illness, such as days lost from work. However, because the NMCUES does not provide death data, the indirect costs of lives lost due to foodborne illness cannot be determined.

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[5]For both the NAMCS and NHDS data, Steahr (1994) used the ICD–9–CM code for GBS (357.0).

[6]The NMCUES Public Use Data Files contain only the National Household Survey data. These data consist of the seven fixed-length data files. The family file is ordered separately, and the remaining six files are ordered as a group.

Table 4—Summary of 1980 National Medical Care Utilization and Expenditure Survey data, by type of file

File type	Information/entry
Header on all files	Participant sequence number
	Stratum and replicate codes
	Basic and time-adjusted weights
	Response status
	Geographic region and standard metropolitan statistical area (SMSA) codes
	Family number and income level
	Age, race, sex, and ethnicity
	Marital status
	Education
	Veteran status and service disability
	Employment in 1980
	Limitation of activity
	Perceived health status
	Insurance coverage by type
	Imputation indicators
Person file (one record per individual)	Interview collection information
	Annual number of:
	Bed days
	Work-loss days
	Cutdown days
	Restricted-activity days
	Medical practitioner visits
	Emergency room visits
	Hospital discharges
	Nights in hospital
	Prescribed medicines
	Other medical expenses
	Total charges and out-of-pocket costs for:
	Medical practitioner visits, by type
	Emergency room
	Outpatient hospital
	Inpatient hospital
	Prescribed medicines
	Other
	Type of insurance by quarter
	Work characteristics
	Income characteristics
	Limitation condition codes
	Medical unattended conditions
	Disability condition codes
	Practitioner office characteristics
	Personal limitations
	Imputation indicators
Medical visit file (one record per visit)	Visit data
	Flat fee amount
	Sources of payment and amount (up to four)
	Condition(s) associated with visit (up to four)
	Type of visit
	Type of clinic
	Place of visit
	Type of physician seen

See notes at end of table.   —Continued

Table 4—Summary of 1980 National Medical Care Utilization and Expenditure Survey data, by type of file—Continued

File type	Information/entry
Medical visit file—Continued	Type of nonphysician seen Type(s) of service (up to three) Type of emergency care Surgery X-rays Laboratory tests Diagnostic procedures Admitted to hospital Imputation indicators
Hospital stay file (one record per hospital stay)	Admission date Flat fee amount Total charge Source(s) of payment and amount (up to four) Condition(s) associated with hospital stay (up to four) Abnormal birth condition(s) (up to four) Nights in hospital Condition at admission Operation(s) performed, by type (up to three) X-rays Laboratory tests Diagnostic procedures Mother sequence number Type of hospital Type of service Number of doctors Type(s) of doctor and flat fee or total charge associated with doctor (up to five doctors and three sources of payment per doctor) Imputation indicators
Prescribed medicine and other expense file (one record per item)	Date Flat fee amount Total charge Source(s) and amount(s) of payment (up to three) Condition(s) associated with medicine (up to three) Type of expense Prescribed medicine code Times obtained Imputation indicators

Dental visit file (one record per visit)	Visit date
	Flat fee amount
	Total charge
	Source(s) and amount(s) of payment (up to 3)
	Type of service:
	  X-rays
	  Teeth cleaned
	  Examination
	  Orthodontia
	  Fillings
	  Extractions
	  Root canals

See notes at end of table.   —Continued

Table 4—Summary of 1980 National Medical Care Utilization and Expenditure Survey data, by type of file—Continued

File type	Information/entry
Dental visit file—Continued	Bridges Dentures Other Imputation indicators

Condition file (up to 3 records for each condition reported)	Type of condition
	Date condition noticed or occurred
	Condition recode
	Number for each condition:
	  Bed days
	  Work-loss days
	  Restricted activity days
	Number and total charges for:
	  Emergency room visits
	  Outpatient department visits
	  Physician visits
	  Hospital stays
	  Prescribed medicines
	Other provider visits
	Outpatient hospital visits
	Reason did not see physician

Family file (one record per family)	Family definition information
	Family beginning date
	Family ending date
	Number of:
	  Bed days
	  Work-loss days
	  Cutdown days
	  Restricted-activity days
	  Medical practitioner visits
	  Emergency room visits
	  Hospital discharges
	  Nights in hospital

Note: The 1980 NMCUES magnetic data tape and microcomputer diskettes can be purchased from the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161 (703–487–4650) or Government Printing Office (202–512–1530).
Source: NCHS, 1994, p. 68.

Strengths and limitations of NMCUES data. Two of the three main components in the NMCUES rely on individuals' recall of illness within their families, rendering the data vulnerable to problems with diagnostic accuracy, because individuals may not know or remember the correct diagnoses. Therefore, information used to determine the appropriate ICD code for each illness may not be very specific. What the household respondent describes as an illness is translated into ICD codes according to guidelines that parallel those used in the National Health Interview Survey (discussed later). Data accuracy depends both on the quality of the information the person received from the medical care provider, and on the person's ability to articulate this information in the surveys

(Harlan et al., 1986). Also, conditions requiring medical treatment were more likely to be remembered and reported than less severe conditions, such as mild gastrointestinal illness (which may possibly account for the bulk of all foodborne illnesses).

The vast majority of foodborne illnesses are not linked to specific pathogens in this data set, due to lack of laboratory data. For example, salmonellosis may be assigned to a more general diarrheal illness category. Due to these problems linking illnesses to ICD codes, the NMCUES data provide limited information on the incidence, prevalence, and severity of foodborne illness in the United States.

Harlan et al. (1986) caution researchers interested in using cost data that total charges reported for some of the prescribed medications, hospital stays, and ambulatory care visits are improbably low. They suggest that the reported data may reflect out-of-pocket expenses incurred by respondents, rather than total charges. Also, for cases where the respondent is treated for more than one condition, it is difficult to isolate costs for a particular illness.

National Health Interview Survey

Probably the most important NCHS survey that provides data on human illness is the National Health Interview Survey (NHIS), implemented annually since 1957.[7] This multipurpose survey provides data on self-reported illness, use of health services, impairments, chronic conditions, and number of restricted-activity days. The survey also provides data on current health-related topics. As with the other previously mentioned data, ICD codes are used. Data on the core component of the survey are available for 1969–93, and on the special supplements (which change from year to year) for 1973–93. The unit of observation is a household.

Sample design. The NHIS uses a multistage probability sample design that provides representative cross-sectional data for U.S. households. The survey excludes U.S. nationals living in foreign countries, persons on active duty with the Armed Forces, and patients in long-term care facilities. Roughly 200 PSU's are randomly drawn from about 1,900 PSU's in the conterminous United States and District of Columbia. PSU's are typically a county or metropolitan area. Within each selected PSU, subareas (or "segments") containing approximately 40 households each are randomly selected. Within each subarea, eight households are drawn for the NHIS sample. Each week throughout the year, an independent sample of more than 800 interviews is conducted by permanent Bureau of the Census personnel.

Since 1985, four panels of PSU's have been formed, each representative of the U.S. population. Not all panels are used every year. Depending on the year, data are collected from roughly 92,000–125,000 persons (less than 1 percent of the U.S. population) in 36,000– 47,000 occupied U.S. households (NCHS, 1994).

The NHIS is a two-part personal interview survey. The first part of the survey is a basic health and demographic questionnaire, repeated each year. The second part is a current health topics questionnaire that varies each year, depending upon an assessment of priority health issues and the associated need for data (such as health insurance and child health). For the basic health and demographic questionnaire (roughly half of the total NHIS), one survey respondent per household is asked to consider a specific 2-week period and to provide information about all acute and chronic illnesses that affected anyone in their household during this time. Specifically, they are asked to consider illnesses that required medical care or restricted activity for at least half a day. Data are also collected on all hospital episodes in the previous 12 months (including length of stay, if surgery was performed). For each survey respondent, data from the basic health and demographic questionnaire are broken into five record types arranged in separate data files: person, household, condition, doctor visit, and hospital (table 5). The person, condition, doctor visit, and hospital groupings are similar to those used in the NMCUES. The household file contains basic household information.

During analysis, NHIS data are adjusted for different probabilities of inclusion and for nonresponses. The data are also poststratified by age, sex, and race, and inflated to obtain national estimates.

The NHIS is useful for those interested in studying the incidence and prevalence of diarrheal illness. Helmick et al. (1994, p. 88) state that the NHIS is the "best available source" of national incidence data for infectious diarrhea. The survey estimates that in the U.S. civilian noninstitutional population in 1988, there were 11.5 million self-reported cases of unspecified intestinal illness (Helmick et al., 1994, p. 88). However, the data provide limited information on illness from foodborne pathogens.

Also, the NHIS does not provide information on the direct costs of foodborne illness. Some indirect costs can be calculated from the days of work missed for those who survive. Yet the lack of death data means that the indirect costs of lost productivity for those who die from foodborne illness cannot be accounted for.[8] This is not a major limitation, however, because almost all patients with foodborne illness survive.

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[7] The 1956 National Health Survey Act provided funding for this survey and the NCHS has administered the survey since 1960.

[8] For the years 1986 to 1990, the NHIS data has been linked to the National Death Index data. Although the yearly sample size is roughly 85,000 persons, there may be only about 1,000 deaths. This is not likely to be a useful data source for studying foodborne illnesses.

Table 5—Summary of 1969–92 National Health Interview Survey data, by type of file

File type	Information/entry

Person record
  Demographic variables
	ID number
	Age
	Sex
	Race (observed 1969–79 and self-reported 1980–92)
	Main racial background (expanded in 1992)
	Born in the United States—number of years lived in State
	  of present residence (1989–92)
	Education of:
	  Individual
	  Family head or reference person
	Family income
	Foreign-born—number of years lived in United States (1989–92)
	Individual income (1978–81)
	Family relationship
	Family size
	Hispanic origin (1978–92)
	Industry
	Main national origin (1977 only)
	Marital status
	MSA or not MSA (1985–92)
	Occupation
	Region
	Respondent (self or proxy)
	Standard metropolitan statistical area (SMSA) or not SMSA
	  residence (1969–84)
	Usual activity
	Veteran status

Health and utilization variables	Annual volumes of:
	  Restricted-activity days
	  Bed days
	  Work-loss days
	  School-loss days
	  Dental visits (1969–81)
	  Doctor visits
	  Hospital days
	Bed days in 12 months (1977–92)
	Interval since last dental visit (1969–81)
	Doctor visits:
	  In the past 12 months
	  Interval since last visit
	Height and weight (1976–92)
	Hospitalization:
	  Number of episodes
	  Days in past 12 months
	Limitation of activity
	Self-assessed health status (1972–92)

Selected variables from supplements	Access to medical care (1977 only) Blood donors (1973 and 1978) Branch of Armed Forces (1978 only) Cigarettes, cigar, and pipe smoking habits (1970 only) Disability payment or benefits received (1977 only)

See notes at end of table.   —Continued

Table 5—Summary of 1969–92 National Health Interview Survey data, by type of file—Continued

File type	Information/entry

Person record—Continued
  Selected variables from supplements—Continued
	Edentulous persons and use of dentures (1971 only)
	Employment:
	  Hours per week, months per year (1979 only)
	  Months at job, work-loss days in 12 months (1977 only)
	Health habits (1977 only)
	Health insurance coverage (January–March and
	  October–December 1970):
	  Medical
	  Hospital
	  Surgical
	Health insurance coverage (1974, 1976, and 1978):
	  Hospital
	  Surgical
	Medicaid use in year (1977–79)
	Orthodontic care (1974 only)
	Preventive care (1973 only)
	Received Medicaid in year (1977 only)
	Service-connected disability (1977–78)
	Single regular source of medical care (1978 only)
	Smoking status: cigarettes smoked a day (1976–77)
	Stroke (1977 only)
	Supplemental Security Income (1978 only)
	Total rooms, bedrooms (1977–78)
	Use of corrective lenses and hearing aids (1971 and 1977)
	Use of special aids (1980 only)
	Veterans Administration medical care in 12 months (1977–78)
	Limitation of mobility:
	  Degree and duration (1972 only)
	  Source of payment for hospitalization and doctor visits (1972
	    only)
	Type of dental service (1971 only)

Household record	Basic household identification

Condition record	ID number
	Same demographic variables as Person Record, with activity
	  limitation status and self-perceived health status (1972–92)
	All conditions:
	  Chronic or acute code
	  Onset
	  Diagnosis
	  Related restricted-activity days:
	    Bed days
	    Work- or school-loss days
	  Whether doctor seen
	  Last seen by doctor
	Selected chronic conditions:
	  Musculoskeletal-skin (1969 and 1976)
	  Respiratory (1970)
	  Impairments (1971 and 1977)
	  Circulatory (1972)
	  Miscellaneous (1973)
	  Digestive (1975)
	  All systems (1978–92)

See notes at end of table.   —Continued

The basic health and demographic questionnaire in the NHIS does not provide cost and payment information. Some current health topic questionnaires, however, obtained cost and payment information (such as sources of payment for hospitalization and doctor visits in 1972, and health insurance coverage in 1974, 1976, and 1978). Harlan et al. (1994, p. 41) state that although the NHIS provides information on some insurance payments and medical charges, "the cross-sectional nature of the NHIS survey design is not well suited for providing annual data on charges and payments."

Table 5—Summary of 1969–92 National Health Interview Survey data, by type of file—Continued

File type	Information/entry

Condition record—Continued	For selected chronic conditions from system lists:
	   Treatment during past 12 months (1969–81)
	   Surgical treatment (1969–81)
	   Hospitalization
	   Doctor visits in past 12 months (1969–81)
	   Frequency and degree of discomfort (1969–81)
	   Current status of condition
	Work-loss days in 12 months (1968–81)
	Bed days in 12 months
	Limitation of activity due to chronic conditions:
	   Overall limitation status
	   Limitation in ability to work (1983–92)
	Injuries:
	   Hospitalization (1969–81)
	   Motor vehicle involved
	   Place of accident

Doctor visit record	ID number Same demographic variables as Person Record, with activity limitation status and self-perceived health status (1972–92) Conditions causing visit Limitation of activity Place of visit Reason for visit (1969–81) Type of doctor Operations performed (1982–92)
Hospital record	ID number Same demographic variables as Person Record, with activity limitation status and self-perceived health status (1972–92) Date of admission Date of discharge Diagnosis (1969–81) Hospital: ownership Hospitalization for delivery (1984–92) Nights in hospital in past 12 months Surgery Type of service (for hospital)

Note: Years available to public are 1969 to 1993 for the core data tapes (though the survey has been conducted since 1957), and 1973 to 1993 for the special options tapes. Data on the basic health and demographic questionnaire can be purchased from the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161 (703–487–4650) and Government Printing Office (202–512–1530). This survey is also available on CD-ROM for the years 1987–1991. Data on NHIS current health topics can be purchased from the Division of Health Interview Statistics, 3700 East-West Highway, Room 2-44, Hyattsville, MD 20782 (301–436–7085).

Source: NCHS, 1994, p. 42.

Strengths and limitations of NHIS data. Although NHIS data do not provide annual cost information, the annual and extensive nature of the survey makes it a potential data source for monitoring trends in the incidence and prevalence of specific foodborne illnesses (those with ICD codes) and for gastrointestinal illness in general. But as with the NMCUES, the coding of ICD and the potential link between an illness and a specific foodborne pathogen hinge on the description of the illness given in the survey by the household respondent. Therefore, it is likely that the majority of foodborne illnesses are coded into one of the general diarrheal illness categories rather than linked to a specific pathogen.

The NHIS data are likely to underestimate the annual cases of foodborne illness because the NHIS focuses on cases that required medical attention and restricted activity for half a day or more (many cases of foodborne illnesses may not restrict activity). Also, the retrospective nature of the survey may mean that respondents may have forgotten episodes of foodborne illness, and they may not have been aware of all cases of foodborne illness in the household, especially when cases were mild.

Other than for foodborne illness cases that result in death, the NHIS provides valuable information on disease severity by recording the number of restricted-activity days, days in hospital, and physician visits. The weekly nature of interviews prevents seasonal bias in the data.

Vital Statistics

"Vital Statistics of the United States" (NCHS, 1990b) is yet another source of national (and State) data that may be used for studying mortality associated with foodborne illness. Although Vital Statistics data are available for marriages, divorces, and births, the information they provide on underlying cause and multiple causes of death is of particular interest for research on foodborne illness.[9] This source provides data on virtually all of the roughly 2.5 million deaths per year in the United States. As with other previously mentioned NCHS data, Vital Statistics data use ICD codes. The unit of observation is a death.

Mortality data are on two separate tapes available to the public: a tape with information on underlying

cause of death; and a more comprehensive tape with information on multiple causes of death, and on the underlying cause of death as well. Both tapes provide information on infant deaths, and a separate linked data tape is available that ties infant births to infant deaths. Another tape available to the public provides information on fetal deaths, but not on cause of death.[10] The multiple-causes-of-death tapes are available for 1968–92, and the tapes with linked files for infants are available for 1983–88. Table 6 provides information on variables found on the different mortality data tapes.

Sample design. Individual States and certain independent registration areas are vested with the responsibility of registering the two NCHS categories of death information: general death (including infant death); and fetal death. Although the NCHS encourages the use of standard certificates, some of these entities add modifications to meet their informational needs, laws, and regulations. For death certificates, physicians or coroners certify deaths (and cause of death), and funeral directors complete the remaining items. All vital events are filed with local registrars, who send the information to State registrars. State registrars check certificates for completeness; index, number, and bind all certificates for permanent filing; and send medical and demographic information to NCHS for national tabulation. As previously described, the NCHS also conducts the NMFS to obtain more data that complements Vital Statistics data; constructs annual life tables using actuarial methods; investigates the reliability and quality of the methodology and data; and integrates legal and technical aspects of the vital statistics registration system (NCHS, 1990a).

Strengths and limitations of Vital Statistics data. One strength of Vital Statistics death data for research on foodborne illness is that all 50 States and the District of Columbia provide death information to NCHS. This comprehensive coverage allows researchers to pull death information for foodborne illnesses with assigned ICD codes. The World Health Organization (WHO) collects the same data from roughly 80 countries, permitting comparisons across countries (Stroup et al., 1994).

The applicability of Vital Statistics data for studying foodborne illness hinges on the relevance of the disease categories used, the completeness of the registration, and the accuracy of the information

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[9]Natality data are not helpful because information on maternal illness consists only of a checkbox of 12 or so items (e.g., hypertension) and none of these items is appropriate here. Additionally, the category on material illness has been in effect only since 1989. Natality data are available from 1968 to 1992.

[10]To get perinatal information, one must combine the fetal death information and information on infants from the underlying cause of death data.

Table 6—Partial summary of Vital Statistics data on mortality

Mortality type	Data
General	Crude, age-adjusted, age-specific death rates Death rates by cause Maternal mortality Deaths for the 50 largest standard metropolitan statistical areas Age Sex Race Hispanic origin Cause of death Month Date of death Report of autopsy Place of death Marital status State or country of birth Status of decedent when death occurred in medical facility

Perinatal	Perinatal deaths, mortality rates, and ratios by race and sex for the:
	  United States
	  Individual States
	  Metropolitan and nonmetropolitan counties

Infant	Number of infant deaths and infant mortality rates by:
	  Age
	  Sex
	  Race
	  Hispanic origin
	  Cause of death
	  State
	  Fifty largest standard metropolitan statistical areas
	Additional tables by month of death and population size groups

Fetal	Number of deaths and ratios by:
	  Sex
	  Age of mother
	  Marital status of mother
	  Geographic areas
	  Population size groups
	  Race
	  Hispanic origin
	Number of deaths by:
	  Month
	  Birth order
	  Attendant
	  Period of gestation
	  Birth weight
	Fetal death rates by sex and plurality

Source: Adapted from NCHS, 1990. Data tapes can be purchased from the National Technical Information Service (5285 Port Royal Road, Springfield, VA 22161 (703–487–4650)) and Government Printing Office (202–512–1530). Prices vary, depending on tape of interest and year. Natality data cost approximately $1,000 to $2,000 per tape, and are available for 1968–1992. 1991 and 1992 fetal death tapes will be released shortly.

provided. Death certificates indicate the underlying cause of death and/or multiple causes of death. Therefore, if two or more foodborne illnesses are listed as multiple causes of death, it is possible to double-count the total number of deaths annually that are attributable to foodborne illness. On the other hand, foodborne deaths may be undercounted because some of the precipitating illnesses may be classified under bacteremia or septicemia. Also, vital-event data often lack specificity. For example, Helmick et al. (1994, p. 86) report that on death certificates, 95 percent of infectious diarrheas do not mention specific diagnoses. In the United States, roughly 1.4 percent of all deaths in 1988 were coded as "signs, symptoms, and ill-defined conditions" (Stroup et al., 1994).

For research on foodborne illness, the main weakness of Vital Statistics death data is that there are very few mentions of foodborne illness. On the multiple-causes-of-death tape for 1987, listeriosis is mentioned 159 times and unspecified food poisoning 6 times. Table 7 shows total number of mentions for some illnesses, although the percentage of each illness that is foodborne cannot be determined. Also, a considerable number of deaths fall into generic categories, and some may be attributable to foodborne illness.

Although Vital Statistics data do not provide information on the direct medical and nonmedical

costs of foodborne illness, death certificates show age at death, which can be used to calculate some of the indirect costs of foodborne illness (that is, lost future productivity for those who die).

Conclusion

The NCHS databases that offer continuing series may permit monitoring of longrun trends in the incidence and prevalence of foodborne illness, although the usefulness of these databases for studying foodborne illness depends largely on whether ICD codes were assigned and how well they were used. Global, non-specific categories may also be useful for information on the characteristics and costs of episodes of diarrheal disease. Overall, the NCHS national databases may offer information that is valuable in assessing differences in foodborne cases by geographical region, sex, race, and other demographic factors. The data can also provide insight into the annual number of preventable foodborne cases and deaths. However, no single database can provide all the information necessary to determine direct medical and nonmedical costs, and indirect costs of lost productivity. Using several databases to compare data on human food-borne illness is suggested.

Table 7—Number of resident deaths from death certificates, tabulated by mention of an underlying cause, of entity axis multiple cause of death by ICD–9 category: United States, 1987

Disease	ICD–9 code	Underlying cause	Total number of mentions
Nontyphoid:			
Salmonella infections--			
Paratyphoid fever	002.9	–	1
Gastroenteritis	003.0	24	61
Septicemia	003.1	61	125
Localized	003.2	5	7
Other	003.8	–	2
Food poisoning (unspecified)	005.4	1	6
Intestinal infection due to other organisms:			
Other specified bacteria	008.4	33	83
Bacterial enteritis, unspecified	008.5	8	10
Viral enteritis	008.6	6	7
Other organisms[1]	008.8	105	178
Listeriosis	027.0	116	159
Septicemia (unspecified)	038.9	16,878	86,580

– = Inadequate sample.

[1]Not elsewhere classified.

Source: Tables from National Center for Health Statistics, Mortality Statistics Branch. Data taken from death certificates.

The national data sources available from NCHS and other Federal agencies, along with limited surveillance data, are widely available to public health investigators at low cost. However, these data sources lack quality and completeness. The data sources described in this paper have major limitations that need to be addressed as surveys and surveillance mechanisms are updated and expanded, and as new data collection efforts to address specific problems are planned. Four limitations are repeatedly named in foodborne disease research:

- Lack of accurate data on the incidence and severity distribution of foodborne illness

- Lack of medical cost data on foodborne illness episodes for which no medical care was sought

- Lack of morbidity data for episodes of foodborne illness

- Underreporting of cases

The lack of accurate data on the incidence of disease derives from four data problems: (1) lack of a specific diagnosis for episodes of enteric illness; (2) incomplete or lacking surveillance for many foodborne pathogens; (3) lack of epidemiological research on modes of transmission, food animal reservoirs, sources on contamination, and impact of drug therapy and its complications; and (4) insufficiently detailed ICD codes.

Most foodborne illness are treated at home without medical consultation. Absence of information on the cost of episodes for which no medical attention was sought is another problem when estimating the cost of foodborne illness: failure to include these costs will lead to a substantial underestimate of the total cost of foodborne illness. Estimates in the literature of episodes where treatment was sought range from 8.3 percent to 43 percent of all cases of foodborne illness (Monto and Koopman 1980; Garthright et al., 1988). In their examination of community and national surveys, Garthright et al. (1988) estimated that only 8.3 percent of intestinal infectious disease resulted in care from a physician. The 1988 NHIS shows that 43 percent of episodes of infectious diarrheas sought medical care. More detailed information is needed on costs of over-the-counter medications, other costs, and productivity losses.

The third limitation of routinely collected data used to estimate foodborne illness costs is lack of information on lost productivity from morbidity associated with foodborne illness. Intestinal infectious diseases, many of which are foodborne, are a major cause of lost productivity in the United States. For cases where medical attention was sought that are captured by data sources described in this paper, information about length of illness and time lost from work is generally not collected. Estimates can be made based on the severity of the illness for which treatment was sought, but these estimates are imprecise without data. However, because of their number, episodes of foodborne illness where no physician was consulted contribute the greatest productivity losses. Brown and Everhart (1992) estimated that in 1985 there were $4.1 billion in productivity losses from episodes of infectious intestinal illness where no physician was consulted. Questions on days lost from work or days of limited activity should be included in national surveys.

The fourth limitation, the underreporting of cases, is due to the inability of health surveys to capture cases of foodborne disease where those afflicted failed to enter the health care system. Data on the cost and distribution of the severity of disease obtained from proposed population-based surveillance networks and outbreak investigations should be routinely collected and disseminated to augment national survey data.

Improving the completeness and quality of data sources will improve estimates of foodborne illness, as will developing new data sources and expanded electronic capabilities. Information sources from the private sector include population-based studies within HMO's, private data sources (such as the MedStat Group's "Marketscan" database from Systemetrics), and cost data from research arms of health management and insurance organizations. For instance, the Center for Health Economics and Policy Research at Blue Cross/Blue Shield has been compiling comprehensive information on the cost of medical treatment. Expanded electronic technology will increase the quality of surveillance systems by improving efficiency in entering and sending data. This will permit expansion of the notifiable disease list with little additional effort.

Although limited in quality and completeness, the routinely collected data sources described in this paper provide low-cost information and can provide background information that will be useful for designing future studies. Efforts must continue to improve and expand information sources for foodborne disease. A complete picture of the economic impact of foodborne illness is a necessary component of studies evaluating the cost-effectiveness of prevention strategies to reduce their incidence in the United States.

Sources and cost-of-data sources described in this paper are listed below. Lists of the variables in the national data sets described in this paper and sources for the data tapes are given in tables 1–7. The appendix contains a comprehensive list of the ICD–9 codes for conditions that may be associated with foodborne disease.

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Appendix:

ICD–9 Codes for Diseases Most Likely Caused by Foodborne Pathogens

001   Cholera
          001.0   Due to *Vibrio cholerae*
          001.1   Due to *Vibrio cholerae el tor*
          001.9   Cholera, unspecified

002   Typhoid and paratyphoid fevers
          002.0   Typhoid fever
                      Typhoid (fever) (infection) [any site]
          002.1   Paratyphoid fever A
          002.2   Paratyphoid fever B
          002.3   Paratyphoid fever C
          002.9   Paratyphoid fever, unspecified

003   Other salmonella infections
     Includes: Infection or food poisoning by Salmonella [any serotype]
          003.0   Salmonella gastroenteritis
                      Salmonellosis
          003.1   Salmonella septicemia
          003.2   Localized salmonella infections
          003.20 Localized salmonella infection, unspecified
          003.21 Salmonella meningitis
          003.22 Salmonella pneumonia
          003.23 Salmonella arthritis
          003.24 Salmonella osteomyelitis
          003.29 Other
          003.8   Other specified salmonella infections
          003.9   Salmonella infection, unspecified

004   Shigellosis
     Includes: Bacillary dysentery
          004.0   *Shigella dysenteriae*
                      Infection by group A *Shigella* (Schmitz) (Shiga)
          004.1   *Shigella flexneri*
                      Infection by group B *Shigella*
          004.2   *Shigella boydii*
                      Infection by group C *Shigella*
          004.3   *Shigella sonnei*
                      Infection by group D *Shigella*
          004.8   Other specified shigella infections
          004.9   Shigellosis, unspecified

005   Other food poisoning (bacterial)
     Excludes: *Salmonella* infections (003.0–003.9)
                      Toxic effect of:
                              Food contaminants (989.7)
                              Noxious foodstuffs (988.0–988.9)
          005.0   Staphylococcal food poisoning
                      Staphylococcal toxemia specified as due to food
          005.1   Botulism
                      Food poisoning due to *Clostridium botulinum*
          005.2   Food poisoning due to *Clostridium perfringens* [*C. welchii*]
                      Enteritis necroticans

005.3   Food poisoning due to other *Clostridia*
005.4   Food poisoning due to *Vibrio parahaemolyticus*
005.8   Other bacterial food poisoning
         Food poisoning due to *Bacillus cereus*
         Excludes: salmonella food poisoning (003.0–003.9)
005.9   Food poisoning, unspecified

006   Amebiasis
       Includes: Infection due to *Entamoeba histolytica*
       Excludes: Amebiasis due to organisms other than *Entamoeba histolytica* (007.8)
006.0   Acute amebic dysentery without mention of abscess
         Acute amebiasis
006.1   Chronic intestinal amebiasis without mention of abscess
         Chronic:
                   Amebiasis
                   Amebic dysentery
006.2   Amebic nondysenteric colitis
006.3   Amebic liver abscess
         Hepatic amebiasis
006.4   Amebic lung abscess
         Amebic abscess of lung (and liver)
006.5   Amebic brain abscess
         Amebic abscess of brain (and liver) (and lung)
006.6   Amebic skin ulceration
         Cutaneous amebiasis
006.8   Amebic infection of other sites
         Amebic:
                   Appendicitis
                   Balanitis
         Ameboma
       Excludes: Specific infections by free-living amebae (136.2)
006.9   Amebiasis, unspecified
         Amebiasis NOS

007   Other protozoal intestinal diseases
       Includes: Protozoal:
                                  Colitis
                                  Diarrhea
                                  Dysentery
007.0   Balantidiasis
         Infection by *Balantidium coli*
007.1   Giardiasis
         Infection by *Giardia lamblia*
         Lambliasis
007.2   Coccidiosis
         Infection by *Isospora belli* and *Isospora hominis*
         Isosporiasis
007.3   Intestinal trichomoniasis
007.8   Other specified protozoal intestinal diseases
         Amebiasis due to organisms other than *Entamoeba histolytica*
007.9   Unspecified protozoal intestinal disease
         Flagellate diarrhea
         Protozoal dysentery NOS

008   Intestinal infections due to other organisms
         Includes: Any condition classifiable to 009.0–009.3 with mention of the responsible organisms
         Excludes: Food poisoning by these organisms (005.0–005.9)
              008.0   *Escherichia coli* [*E. coli*]
                       008.00   *E. coli*, unspecified
                                E. coli enteritis NOS
                       008.01   Enteropathogenic *E. coli*
                       008.02   Enterotoxigenic *E. coli*
                       008.03   Enteroinvasive *E. coli*
                       008.04   Enterohemorrhagic *E. coli*
                       008.09   Other intestinal *E. coli* infections
              008.1   Arizona group of paracolon bacilli
              008.2   *Aepobacter cerogenes*
                       Enterobacter aerogenes
              008.3   *Proteus* (*mirabilis*) (*morganii*)
              008.4   Other specified bacteria
                       008.41   *Staphylococcus*
                                Staphylococcal enterocolitis
                       008.42   *Pseudomonas*
                       008.43   *Campylobacter*
                       008.44   *Yersinia enterocolitica*
                       008.45   *Clostridium difficile*
                                Pseudomembranous colitis
                       008.46   Other anaerobes
                                Anaerobic enteritis NOS
                                Gram-negative anaerobes
                                Bacteroides (*fragilis*)
                       008.47   Other gram-negative bacteria
                                Gram-negative enteritis NOS
                                Excludes: gram-negative anaerobes (008.46)
                       008.49   Other
              008.5   Bacterial enteritis, unspecified
              008.6   Enteritis due to specified virus
              008.61   Rotavirus
              008.62   Adenovirus
              008.63   Norwalk virus
                       Norwalk-like agent
              008.64   Other small round viruses (SRV's)
                       Small round virus NOS
              008.65   Calcivirus
              008.66   Astrovirus
              008.67   Enterovirus NEC
                       Coxsackie virus
                       Echovirus
                       Excludes: poliovirus (045.0–045.9)
              008.69   Other viral enteritis
                       Torovirus
              008.8   Other organisms, not elsewhere classified
                       Viral:
                                Enteritis NOS
                                Gastroenteritis
                       Excludes: Influenza with involvement of gastrointestinal tract (487.8)

009   Ill-defined intestinal infections
        Excludes: Diarrheal disease or intestinal infection due to specified organism (001.0–008.8)
                               Diarrhea following gastrointestinal surgery (564.4)
                               Intestinal malabsorption (579.0–579.9)
                               Ischemic enteritis (557.0–557.9)
                               Other noninfectious gastroenteritis and colitis (558.1–558.9)
                               Regional enteritis (555.0–555.9)
                               Ulcerative colitis (556)
        009.0   Infectious colitis, enteritis, and gastroenteritis
                Colitis (septic)
                Enteritis (septic)
                Gastroenteritis (septic)
                Dysentery:
                        NOS
                        Catarrhal
                        Hemorrhagic
        009.1   Colitis, enteritis, and gastroenteritis of presumed infectious origin
                Excludes: Colitis NOS (558.9)
                           Enteritis NOS (558.9)
                           Gastroenteritis NOS (558.9)
        009.2   Infectious diarrhea
                Diarrhea:
                        Dysenteric
                        Epidemic
                Infectious diarrheal disease NOS
        009.3   Diarrhea of presumed infectious origin
                Excludes: Diarrhea NOS (558.9)

027.0   Listeriosis
                Infection by *Listeria monocytogenes*
                Septicemia by *Listeria monocytogenes*
                Use additional code to identify manifestations, such as meningitis (320.7)
        Excludes: Congenital listeriosis (771.2)

070   Viral hepatitis
        Includes: Viral hepatitis (acute) (chronic)
        Excludes: Cytomegalic inclusion virus hepatitis (078.5)

        The following fifth-digit subclassification is for use with categories 070.2 and 070.3:

        0   Acute or unspecified, without mention of hepatitis delta
        1   Acute or unspecified, with hepatitis delta
        2   Chronic, without mention of hepatitis delta
        3   Chronic, with hepatitis delta

                070.0   Viral hepatitis A with hepatic coma
                070.1   Viral hepatitis A without mention of hepatic coma
                        Infectious hepatitis
                070.2   Viral hepatitis B with hepatic coma
                070.3   Viral hepatitis B without mention of hepatic coma
                        Serum hepatitis
                070.4   Other specified viral hepatitis with hepatic coma
                        070.41   Acute or unspecified hepatitis C with hepatic coma
                        070.42   Hepatitis delta without mention of active hepatitis B disease with hepatic coma
                                 Hepatitis delta with hepatitis B carrier state
                        070.43   Hepatitis E with hepatic coma

070.44   Chronic hepatitis C with hepatic coma
070.49   Other specified viral hepatitis with hepatic coma
070.5   Other specified viral hepatitis without mention of hepatic coma
070.51   Acute or unspecified hepatitis C without mention of hepatic coma
070.52   Hepatitis delta without mention of active hepatitis B disease or hepatic coma
070.53   Hepatitis E without mention of hepatic coma
070.54   Chronic hepatitis C without mention of hepatic coma
070.59   Other specified viral hepatitis without mention of hepatic coma
070.6   Unspecified viral hepatitis with hepatic coma
070.9   Unspecified viral hepatitis without mention of hepatic coma
Viral hepatitis NOS

123.1   Cysticercosis
Cysticerciasis
Infection by Cysticercus cellulosae (larval form of Taenia solium)

124   Trichinosis
Trichinella spiralis infection
Trichinellosis
Trichiniasis

558.9   Other and unspecified noninfectious gastroenteritis and colitis
Colitis, NOS, allergic, dietetic, or noninfectious
Diarrhea, NOS, allergic, dietetic, or noninfectious
Enteritis, NOS, allergic, dietetic, or noninfectious
Gastroenteritis, NOS, allergic, dietetic, or noninfectious
Ileitis, NOS, allergic, dietetic, or noninfectious
Jejunitis, NOS, allergic, dietetic, or noninfectious
Sigmoiditis, NOS, allergic, dietetic, or noninfectious

988   Toxic effect of noxious substances eaten as food
Excludes: Allergic reaction to food, such as:
Gastroenteritis (558.9)
Rash (692.5, 693.1)
Food poisoning (bacterial) (005.0–005.9)
Toxic effects of food contaminants, such as:
Aflatoxin and other mycotoxin (989.7)
Mercury (985.0)
988.0   Fish and shellfish
988.1   Mushrooms
988.2   Berries and other plants
988.8   Other specified noxious substances eaten as food
988.9   Unspecified noxious substances eaten as food

An Estimate of Risk of Foodborne Illness for Persons with HIV/AIDS Infection, United States, 1987–92

Thomas E. Steahr
University of Connecticut

Statement of the Problem

During the past several years, there has been an increasing awareness of foodborne illness as a health problem in the United States. In a recent definitive report, the Council for Agricultural Science and Technology summarized the state of knowledge of this problem (Council for Agricultural Science and Technology, 1994). Factors associated with foodborne pathogens included hazard identification, dose response assessment, exposure assessment, estimated numbers of illness, economic costs, and prevention of foodborne illness. In addition, it is recognized that in the United States an increasing percentage of the population is becoming especially susceptible to pathogens causing foodborne illness (Council for Agricultural Science and Technology, 1994, pp. 25–26). Specifically, high-risk groups include pregnant women, elderly persons, cancer patients, organ transplant patients, and human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) patients. Missing in this review of the state of knowledge of foodborne illness is an analysis of the strength of the relationship between foodborne illness of various types and HIV/AIDS illness.

The growing epidemic of HIV infection in the United States is documented (Kozak, 1993). Continuous surveillance is accomplished by the National Centers for Infectious Diseases, Centers for Disease Control and Prevention, and the *HIV/AIDS Surveillance* reports issued regularly (USDHHS CDC, various years to 1992). In terms of four common foodborne pathogens, *Salmonella* spp., *Listeria, Campylobacter jejuni,* and *Vibrio* spp., a recent review of the medical literature has documented higher risks of illness in HIV-infected individuals as a consequence of ingesting contaminated food (Altekruse et al., 1990). In the United States, the reported rate of nontyphi salmonellosis in HIV-infected persons is significantly higher than that for the general population (Celum et al., 1987; Sperber et al., 1987). The prevalence of listeriosis is higher in people with AIDS or HIV infection than in the general population (Kales et al., 1990), and major clinical symptoms of AIDS-associated listeriosis are bacteremia and acute meningitis (Harvey et al., 1988). Persons with AIDS are at elevated risk for infection due to *Campylobacter jejuni* and from infection due to *Vibrio* ssp. (Altekruse et al., 1990). In view of these and related reports, it is suggested that patients be counseled to avoid food with high risk of holding bacterial pathogens

(Archer, 1989), and that basic rules for safe food preparation be followed to reduce the risk of illness for HIV/AIDS patients (Altekruse et al., 1990).

At the individual level of analysis, surveillance data are critical to document patterns of incidence and prevalence of foodborne and waterborne illness. However, national patterns and trends over time require aggregate data for populations. This report deals with patterns of foodborne illness and HIV/AIDS trends in the United States and provides initial consideration of the demographic characteristics associated with elevated risk of foodborne illness for populations with HIV/AIDS infection. It is not the intent to determine if certain illness conditions, such as gastroenteritis, are primarily the result of exposure to foodborne pathogens, or whether these conditions may appear without exposure to foodborne pathogens due to complications of the HIV infection itself. The answer to that important question extends beyond the purpose and the data for this report. However, it is the intent to describe trends and demographic patterns in the national population for foodborne illness and its elevated risk for HIV/AIDS-infected persons.

Data and Methods

The first step is to derive a list of diseases that link the agents causing foodborne/waterborne illness with persons suffering from these diseases so that appropriate demographic analysis may be performed. Based on a selection of International Classification of Diseases (ICD) 9–3 codes (Karaffe, 1992) for diseases most likely to be caused by foodborne/waterborne pathogens, the following working list is used to define foodborne illness in this analysis (Steahr, 1994):

Disease Category	ICD–9 Code
Cholera	001.0–001.9
Typhoid	002.0–002.9
Salmonellosis	003.0–003.9
Shigellosis	004.0–004.9
Food poisoning	005.0–005.9
Amebiasis	006.0–006.9
Protozoal intestinal disease	007.0–007.9
Intestinal infections due to other organisms	008.0–008.8

Disease Category	ICD–9 Code
Ill–defined intestinal infections	009.0–009.3
Listeriosis	027.0
Viral hepatitis A	070.0, 070.1, 070.9
Cysticercosis	123.1
Trichinosis	124
Unspecified gastroenteritis and colitis	558.9
Noxious substances eaten as food	988.0–988.9

This list includes most of the diseases caused by foodborne infectious agents—bacterial, parasitic, and viral (Helmick et al., 1994). It is recognized that not all of the cases of diseases included in this list are caused by foodborne or waterborne vehicles. For example, not all of the cases of unspecified gastroenteritis and colitis are caused by foodborne or waterborne vehicles, nor are all of the cases of ill-defined intestinal infections. In addition, certain other diseases are not included because the proportion of the cases caused by foodborne pathogens is unknown. For example, some of the cases of illness contained in the category "Bacterial Infection in Conditions Classified Elsewhere" and "Unspecified Site" (ICD–9 Code 041.0–041.9) are caused by foodborne/ waterborne pathogens. The same is true for "Cestode Infections" (ICD–9 Code 123.0–123.9), "Intestinal Helminthiases" (ICD–9 Code 127.0–127.9), and "Toxoplasmosis" (ICD–9 Code 130.0–130.9). In view of these and other limitations, the working definition of gastroenteritis used in this report underestimates the actual level of disease. The complexity of identifications of foodborne and waterborne disease is recognized (Council for Agricultural Science and Technology, 1994) and extends well beyond the intent of this report. Foodborne pathogens, however, do play a major role in causing gastroenteritis (Helmick et al., 1994).

The identification of HIV/AIDS–infected persons is based on ICD–9 Codes 279.19, 042.0–042.9, 043.0–043.9, 044.0–044.9, and 795.8. Code 279.19 was the only code to classify patients with AIDS prior to 1986. Code 795.8, "Positive HIV Serological or Viral Culture Findings," was added in 1986. ICD–9 Code 042, "Human Immunodeficiency Virus Infection With Specified Conditions," includes AIDS. ICD–9 Code 043, "Human Immunodeficiency Virus Infection Causing Other Specified Conditions," includes AIDS-like syndrome, and AIDS-related complex. ICD–9 Code 044, "Other Human Immunodeficiency Virus Infection," includes infections that cause specified acute infections due to HIV infection and unspecified human immunodeficiency virus infection. A final consideration is that data from the National Hospital Discharge Survey (NHDS) described later does not allow a separate analysis for HIV-positive and AIDS patients

discharged from hospitals. Therefore, the two groups are analyzed as one statistical category, even though people react differently to foodborne pathogens depending on the length of HIV infection. Clearly, persons with advanced AIDS infection will be at higher risk of foodborne illness and find it more difficult to deal with than persons with recent HIV infection. Refinements such as this require a different statistical database than any used here.

The data providing this information are found in the NHDS described later. It is important to realize that (a) not all persons with HIV/AIDS infections are admitted into hospitals, and (b) hospital discharge certificates do not equal the number of patients because one person may be admitted into and discharged from the hospital several times during the year. This inequality may be greater for persons with serious health conditions requiring treatment in hospitals, which may result in the patient records being drawn more than once in the sampling. Given the problem of inequality between discharge certificates and patients, the rates shown in this report are based on all hospital discharge certificates per 1,000 and not on cases per 100,000 total population in the United States.

Data for patient illness used in this report are drawn from the NHDS from 1987 to 1992 (the most recent year available), provided by the Centers for Disease Control and Prevention, National Center for Health Statistics (USDHHS CDC, 1987–92). While these annual surveys differ slightly in terms of sample size and other details, they are basically drawn from the same sampling universe. They cover discharges from noninstitutional hospitals located in the United States (excluding Federal, military, and Veterans' Administration hospitals). Only short-stay (average length of stay less than 30 days) or children's general hospitals are included. These hospitals also must have six or more beds staffed for patient use to qualify for the survey. The medical information for each patient discharged from the hospital was taken from the sample patient abstracts. A maximum of seven diagnostic codes were assigned for each abstract. In addition, a maximum of four codes for surgical or nonsurgical procedures were assigned. The coding system used is the "International Classification of Diseases," 9th revision, clinical modification 3. The estimated size of the universe sampled and the total sample size each year is (estimate of all hospital discharges in the United States (NHDS)):

Year	Certificates	Sample Size
1992	34,639,425	274,273
1991	34,977,668	274,311
1990	34,660,000	265,556
1989	34,800,000	233,493
1988	34,880,000	250,243
1987	37,360,000	180,982

The samples or actual observations are weighted to provide an estimate of the true population parameter, and therefore have relative standard errors (RSE's) associated with them at given confidence levels. Estimates based on fewer than about 20 sample observations are either not shown in this report or shown with very large RSE's. Since the purpose is to establish general trends of foodborne illness and patterns of HIV/AIDS infections with foodborne illness over time, the analytical limitations of small samples will not constitute a major problem. Using the ICD-9 codes described above, lines 1-7 of the hospital discharge certificates (HDC's) were examined for foodborne illness and HIV infections. The characteristics of patients meeting these conditions are presented below.

Findings: Basic Trends in the United States

The basic trends in the United States are shown in table 1. The trend in mentions of foodborne illness in the Nation has fluctuated within a relatively narrow range, from a low of about 725,000 in 1988 to a high of about 813,000 in 1992. The RSE's at the 68-percent confidence intervals are reasonably small at about 4 percent. The upper and lower confidence limits may be calculated by multiplying the RSE times the number under examination and adding that amount to or subtracting it from the number. The 68-percent confidence intervals were judged adequately precise for this report, given the problems

with the data described above. The rate of foodborne illness involving hospitalizations is increasing slightly over time, moving from 20.5 per thousand hospital discharges in 1987 to 23.5 per thousand hospital discharges in 1992.

Table 1 also shows the number of discharge certificates from 1987 to 1992 with mention of HIV/AIDS infection on lines 1-7. Unlike the trend for foodborne illness, both the number and rate of HIV/AIDS mentions are increasing steadily. The number of certificates with mentions of HIV/AIDS infection grew from 66,571 in 1987 to 193,693 in 1992, a significant increase during the 5-year period. The RSE's are in the 7 to 6 percent range, a reasonable margin of error. The rate of mentions of HIV/AIDS infections on all HDC's also increased from 1.8 per thousand in 1987 to 5.6 per thousand in 1992. This steady pattern suggests that additional data may show a continuation of the upward trend in the number and rate of HIV/AIDS infections recorded on HDC's.

However, it should be noted that for all HDC's from 1987 to 1992, the mention of foodborne illness is more frequent than the mention of HIV/AIDS infection by a factor of about 4 in 1992.

Counts of HDC's with mention of foodborne illness and HIV/AIDS infections revealed a steady increase from

Table 1—Hospital discharge certificates, mention of foodborne illness,[1] HIV/AIDS infection, and foodborne illness with HIV/AIDS infection, United States, 1987–92

Year	Mentions of foodborne illness			Mentions of HIV/AIDS infection			Mentions of foodborne illness with HIV/AIDS infection			Odds ratio	Confidence intervals[5]	
											Lower limit	Upper limit
	Number	RSE[2]	Rate[3]	Number	RSE[2]	Rate[3]	Number	RSE[2]	Rate[4]			
1992	813,091	3.9	23.5	193,693	5.7	5.6	17,645	16.2	91.1	4.2	4.1	4.3
1991	791,197	4.1	22.6	165,564	6.5	4.7	17,592	17.9	106.3	5.2	5.1	5.3
1990	805,733	5.5	23.2	146,801	6.1	4.2	13,667	10.3	93.1	4.2	4.2	4.4
1989	759,228	5.9	21.8	140,613	7.9	4.1	9,434	23.2	67.1	3.3	3.1	3.3
1988	724,942	4.6	20.8	95,591	7.6	2.7	9,111	21.4	95.3	5.1	4.9	5.1
1987	766,956	4.1	20.5	66,571	6.1	1.8	4,832	19.1	72.6	3.8	3.6	3.9

Note: Mentions are counted from lines 1-7 on the discharge certificate.
[1]See text for working definition of foodborne illness.
[2]RSE = relative standard of error of the number of mentions, expressed as a percent (i.e., RSE times number of mentions gives upper and lower limits of the estimate at the 68-percent confidence intervals).
[3]Based on all hospital discharge certificates per thousand.
[4]Number of mentions of foodborne illness with HIV/AIDS infection divided by all mentions of HIV/AIDS infection per thousand.
[5]At the 95-percent confidence level.
Source: USDHHS CDC, National Hospital Discharge Survey.

4,832 in 1987 to 17,645 in 1992, the largest number yet recorded. Expressing this increase in relative terms to allow comparisons from year to year is accomplished by dividing the number of foodborne illness with HIV/AIDS infections by the number of HIV/AIDS mentions. In other words, the 17,645 HDC's with mention of both foodborne illness and HIV/AIDS is divided by the 193,693 certificates with mention of HIV/AIDS and multiplied by 1,000. In 1992, there are 91.1 certificates with mention of both foodborne illness and HIV/AIDS per thousand certificates with mention of HIV/AIDS infection. This could be expressed as 9.11 percent of all HIV/AIDS mentions if the constant was 100. Unlike the trend for the number of certificates with mention of both foodborne illness with HIV/AIDS, the pattern for the rate is not always upward. In 1987, the rate was 72.6 per thousand certificates with mention of HIV/AIDS, and then increased to 95.3 per thousand the following year in 1988, after which the rate fell to its lowest level of 67.1 per thousand in 1989. Over the next 2 years, the rate increased to 106.3 per thousand, and then declined to 91.1 mentions of foodborne illness with HIV/AIDS infection per thousand discharge certificates with mention of HIV/AIDS infection.

While the number and rate of mentions discussed above identify the patterns of change over time, they do not deal with the risk of being sick with foodborne illness and HIV/AIDS infection. One important way to quantify the relative risk or association between foodborne illness and HIV/AIDS infections is to calculate the "odds ratio" for these two factors. If foodborne illness is viewed as the risk factor and HIV/AIDS is viewed as the related condition, a 2-by-2 table may be constructed to show the presence or absence of foodborne illness by the presence or absence of HIV/AIDS infection. The odds ratio relates the odds of being a case (foodborne illness with HIV/AIDS) to not being a case for those with and without the risk factor (Kahn, 1983, p. 43). In this report, the odds ratio is only taken to suggest the association between the two factors in a retrospective analysis and is subject to standard constraints of this method (Anokute, 1991). The odds ratio is interpreted as an indication of the elevated risk of foodborne illness for patients with HIV/AIDS infections. While it is likely that the findings presented below are largely influenced by AIDS patients with the most seriously compromised immune systems compared to patients testing positive for HIV infection, it is not possible to analyze the groups independently.

In table 1, the data for 1987 show that the odds ratio is 3.8. That means that HDC's in 1987 with mention of HIV/AIDS infection have 3.8 times more risk of foodborne illness than certificates without mention of HIV/AIDS infection. The pattern is irregular during the time period, with an increase to 5.1 in 1988 followed by a

decline to 3.3 in 1989. After 1989, there is an annual increase that reached 5.2 in 1991. The ratio declined to 4.2 in 1992. Some of this variation is due to sampling variability and differences in the RSE of the estimate of foodborne illness. However, this is evidence of a higher risk of foodborne illness for certificates with mention of HIV/AIDS infection. This risk is 4 to 5 times higher than for certificates without mention of HIV/AIDS infection.

Patterns by Age in the United States for 1992

In order to further identify the demographic factors related to higher risk of foodborne illness, table 2 shows data for HDC's with mention of foodborne illness, HIV/AIDS infection, and foodborne illness and HIV/AIDS infection by age for the Nation in 1992. Several patterns are present in these data. First, the largest number of foodborne illness mentions is concentrated in young patients under 15 years of age and in elderly patients 65 years of age and over. The RSE's for the young age groups are large, which means that sampling variability could account for some of the size of this estimate of foodborne illness. The rate of foodborne mentions by age per thousand HDC's shows a similar pattern but, unlike the basic numbers, the rates are relatively high for the middle ages of 35–74 years, ranging around 21 mentions of foodborne illness per thousand HDC's. The highest rate is 59.8 mentions of foodborne illness per thousand HDC's in 1992 for children 5 to 14 years of age.

Also shown in table 2 for 1992 is the age pattern of discharge certificates with mention of HIV/AIDS infections. There is a heavy concentration in the age groups 25–34, 35–44, and 45–54. Of the total of 193,693 certificates with mention of HIV/AIDS infection, 169,422 (87.5 percent) are in those three age groups. The RSE for these age groups is a relatively small 11 percent. It should be noted that when the age of the patient is considered, discharge certificates with mention of foodborne illness far outnumber those with mention of HIV/AIDS infection. That is the case for all age groups, except for the 35- to 44-year-olds. In that age group, there are more HIV/AIDS mentions (82,442) than foodborne illness mentions (69,783) on the certificates. The younger age group of 25–34 years of age recorded slightly fewer HIV/AIDS mentions (68,160) than foodborne illness mentions (79,053). When these numbers are expressed as a rate per thousand HDC's, the concentration is more pronounced. For patients 25 to 34 years old, the rate of mention of HIV/AIDS infection is 14.8 per thousand certificates. For patients 35 to 44 years of age, the rate of mention of HIV/AIDS infection is 24.8 per thousand certificates, exceeding the rate of foodborne illness mentions. All other age groups have rates at the single-digit level.

Table 2—Hospital discharge certificates, mention of foodborne illness, HIV/AIDS infection, and foodborne illness with HIV/AIDS infection by age, United States, 1992

Age	Mentions of foodborne illness			Mentions of HIV/AIDS infection			Mentions of foodborne illness with HIV/AIDS infection			Odds ratio
	Number	RSE[1]	Rate[2]	Number	RSE[1]	Rate[2]	Number	RSE[1]	Rate[3]	
0–4	192,781	24.7	38.3	5,801	27.4	1.1	704	42.1	121.9	n.a.
5–14	54,016	24.9	59.8	2,723	30.1	3.1	256	n.a.	n.a.	n.a.
15–24	46,175	11.8	14.1	7,988	13.6	2.4	210	n.a.	n.a.	n.a.
25–34	79,053	12.1	17.1	68,160	11.6	14.8	7,297	13.8	107.1	7.5
35–44	69,783	11.6	21.1	82,442	11.6	24.8	7,064	13.9	85.7	4.8
45–54	65,267	9.4	22.4	18,820	8.1	6.5	1,989	28.4	105.7	5.3
55–64	65,849	9.4	19.2	6,077	17.6	1.8	69	n.a.	n.a.	n.a.
65–74	99,038	8.1	20.3	1,100	65.1	0.2	57	n.a.	n.a.	n.a.
75+	141,129	7.1	23.6	582	n.a.	0.1	0	0	0	0
Total	813,091	3.9	23.5	193,693	35.7	5.6	17,645	16.2	91.1	4.2

n.a. Not applicable and statistics not reported.
Note: Mentions are counted from lines 1–7 on the discharge certificate.
[1]RSE = relative standard of error of the number of mentions, expressed as a percent (i.e., RSE times number of mentions gives upper and lower limits of the estimate at the 68-percent confidence intervals).
[2]Based on all hospital discharge certificates.
[3]Number of mentions of foodborne illness with HIV/AIDS infection divided by all mentions of HIV/AIDS infection per thousand.
Source: USDHHS CDC, National Hospital Discharge Survey.

The third major pattern shown in table 2 is for certificates with mention of foodborne illness and HIV/AIDS infection. Of the total of 17,645 cases in 1992, a majority of 16,350 (92.7 percent) are in the 25 to 54 age interval. However, the RSE for the 45- to 54-year-olds is 28.4 percent, which is a wide confidence interval. This suggests that the 25- to 34-year olds and the 35- to 44-year-olds have the highest number of cases. In terms of relative risk of foodborne illness, the odds ratio shows that certificates with mention of HIV/AIDS have a 7.5 times greater risk than do certificates without mention of HIV/AIDS infection for patients 25 to 34 years of age. For patients 35 to 44 years of age, the odds ratio is 4.5. For patients in the 45- to 54-year age group, the odds ratio is 5.3.

Trends by Age in the United States from 1988 to 1992

The pattern of statistical analysis as presented above for table 2 was accomplished separately for 1991, 1990, 1989, 1988, and 1987. These tables are available by request to the author. Rather than discuss each of these tables, the important trends are summarized in figures 1 through 4, based on data for 1988, 1990, and 1992. Figure 1 shows the rate of foodborne illness mentions on all HDC's by the age of the patient in the United States. This rate is expressed as foodborne illness mentions per thousand HDC's. It is immediately clear that the highest

Figure 1

Rates of mentions of foodborne illness on hospital discharge certificates, by age, United States, 1988 to 1992
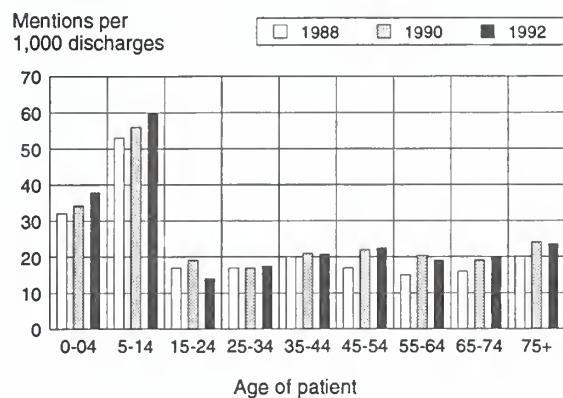
foodborne illness rates are for young patients under 15 years of age, a pattern described for 1992. It is also apparent that this concentration in the younger ages is increasing over the period, especially for children 5 to 14 years of age. The middle age groups, from 15 to 44 years of age, show a relatively stable pattern of rates

of foodborne illness mentions on HDC's, about 18 to 20 mentions per thousand certificates. The older groups of 45 to 74 years of age show a gradual increase in rates of mentions, although not as large as for the younger age groups.

Figure 2 presents data on the rate of mentions of HIV/ AIDS infection on all HDC's by age of the patient from 1988 to 1992 in the United States. These patterns are in sharp contrast to those described for foodborne illness mentions. The two dominant patterns are that the rates of HIV/AIDS mentions are concentrated in the middle ages of 25 to 34, 35 to 44, and 45 to 54, and secondly, that this pattern of concentration is increasing during the time period for each of the three age intervals. Patients with mention of HIV/AIDS infection in the age group of 35 to 44 years show the largest increase in their rates, moving from 11.5 per thousand in 1988 to 24.8 per thousand discharge certificates in 1992. That rate of HIV/AIDS mentions exceeds the rate for foodborne illness mentions in that age group in 1992.

Additional data not presented here revealed that the majority of cases in each age group are men. For patients 25–34 years of age with mention of HIV/AIDS infection on the discharge certificate, 82 percent were male in 1992. For patients 34 to 44 years of age in this category, 84 percent were male and for patients 45 to 54 years of age, 82 percent were male. Moreover, within these discharge certificates with mention of HIV/AIDS infection, the largest proportion were not married males (never married, widowed, divorced, separated, or unknown). In 1992, for example, 96 percent of the males with mention of HIV/AIDS infection 25 to 34 years of age were not married. In addition, 94 percent of the males in the 35- to 44- and 45- to 54-year-old groups were not married.
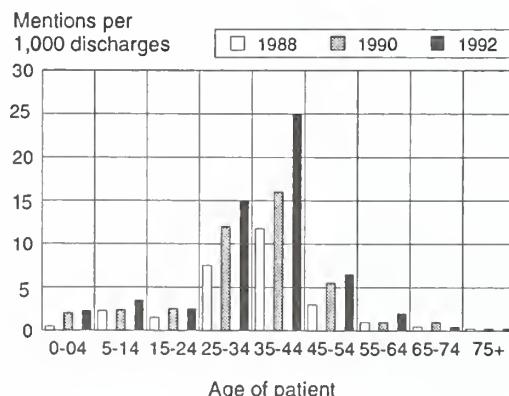
Figure 3 presents data on the rate of mentions of food-borne illness with HIV infection per thousand certificates with mention of HIV/AIDS infection from 1988 to 1992 by age of patient. Unlike the previous data, these rates are not based on all HDC's but rather certificates with mention of HIV/AIDS infection in order to make compar-isons over time in the risk of foodborne illness among HIV/AIDS patients. There are basically three distinct trends. For patients 25 to 34 years of age, the rate of foodborne illness with HIV infections increased slightly from 96.2 per thousand certificates with mention of HIV/AIDS infection to 107.1 per thousand certificates with HIV/AIDS in 1992. This is a high level, which is increasing slowly during the time interval. The next age group of 35 to 44 years of age shows an irregular pattern of decline from a rate of 107.4 in 1988 to 81.4 in 1990, which is followed by an increase to 85.7 in 1992. The oldest age interval of patients 45 to 54 years of age shows the most dramatic increase in their rates of food-borne illness for patients with HIV/AIDS infections. The rate in 1988 was 51.3 per thousand certificates with mention of HIV/AIDS infection. In 1990, the rate of foodborne illness for patients with HIV/AIDS infection jumped to 95.5 per thousand patients with HIV infection. In 1992, the rate increased to 105.7 per thousand patients with HIV/AIDS infection.

Figure 4 contains data on the odds ratio for foodborne illness with HIV/AIDS infection by age of the patient from 1988 to 1992 in the United States. Only the three age groups discussed above are shown in this graph. One pattern that is clear is that patients 25 to 34 years old with mention of HIV/ AIDS infection have the highest risk of foodborne illness of all age groups. While they are the highest risk group, the odds ratios have been

Figure 2
Rate of mentions of HIV infection on hospital discharge certificates, by age, United States, 1988 to 1992

Figure 3
Foodborne illness with mention of HIV infection per 1,000 HIV patients, by age, United States, 1988 to 1992
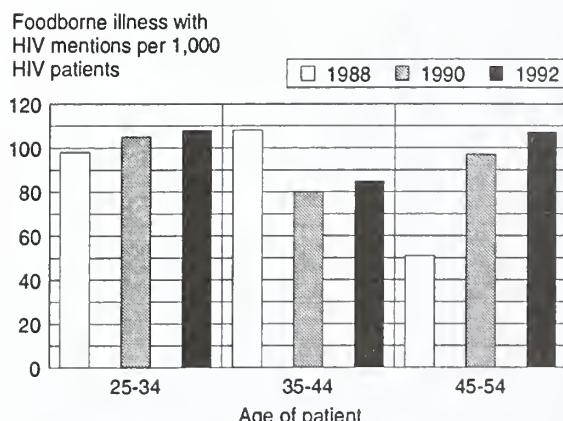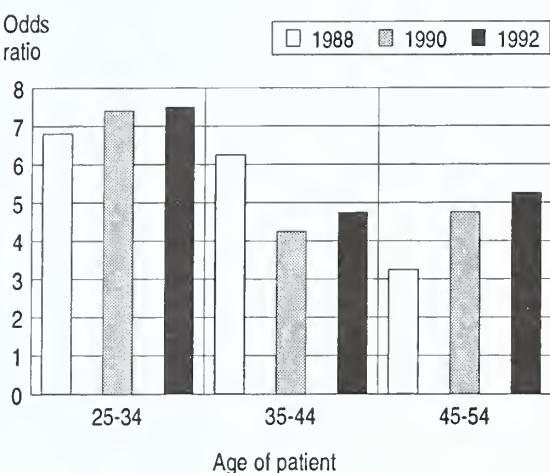
Figure 4
Odds ratio for foodborne illness with mention of HIV infection on hospital discharge certificates, by age, United States, 1988 to 1992

Age of patient

remaining stable since 1990. In 1992, the HDC's for this age group with mention of HIV/AIDS infection had a 7.5 times greater risk of foodborne illness than certificates without mention of HIV/AIDS infection. The next group of 35 to 44 years of age shows an irregular pattern of declines in the odds ratio, from 6.3 in 1988 to 4.3 in 1990. By 1992, the odds ratio had increased to 4.8. The basic trend for this age group seems to be one of an elevated but stable odds ratio at about a 4.5 level. The last age group of 45 to 54 years of age shows a trend of increases in their odds ratio. They moved from a ratio of 3.2 in 1988 to 4.8 in 1990 to 5.3 in 1992. This means that the HDC's with mention of HIV/AIDS infection had a 5.3 times greater risk of foodborne illness than certificates without mention of HIV/AIDS infection for this age group in 1992.

The examination of data not contained in this report reveals a pattern similar to that described for HIV/AIDS mentions, namely that the HDC's with foodborne illness with mention of HIV/AIDS infection are primarily for male patients who are not married. For example, of those discharge certificates with foodborne illness with mention of HIV/AIDS infection 25 to 34 years of age in 1992, 81 percent were unmarried males. For the age group of 35 to 44 years in the category, 89 percent were unmarried males, and in the next group of 45 to 54 years, 93 percent were unmarried males.

Trends in Type of Foodborne Illness with HIV Infection

Using the working list of foodborne illnesses described above, table 3 presents data on the number of HDC's

with mention of foodborne illness and HIV/AIDS infection by type of foodborne disease in the United States from 1988 to 1992. A total of nine ICD–9 codes contained cases of foodborne illness with HIV/AIDS infection. However, ICD–9 Code 558.9, "Unspecified Gastroenteritis and Colitis," a group of clinical symptoms, including upper GI tract problems, diarrhea, and abdominal pain, contains the most cases. Since this is a generic term, it implies that the etiology is uncertain or unknown. However, certain diseases of known bacterial, viral, or parasitic etiology can be included in the category. *Campylobacter* infections are being recognized as a cause of gastroenteritis and as a common bacterial cause of diarrheal illness (Berkow and Fletcher, 1992, p. 813). The Norwalk virus is a major cause of nonbacterial diarrhea and is usually spread via contaminated water or food (Berkow and Fletcher, 1992, p. 813). Intestinal parasites, such as *Giardia lamblia*, also cause nausea, vomiting, and diarrhea, and may be transmitted indirectly via contamination of water or food (Berkow and Fletcher, 1992). This generic category of disease contained 64.7 percent of all foodborne illness with HIV/AIDS mentions in 1992 and contained over half of all cases in each of the other years, except 1988.

The balance of the cases of foodborne illness with HIV/AIDS mention are distributed over the remaining categories. Intestinal infections due to other organisms contained 16 percent of the cases, protozoal intestinal disease contained 7 percent of the cases, as did ill-defined intestinal infections. *Salmonella* infection accounted for 2.5 percent of all these cases in 1992, and viral hepatitis A contained 1.2 percent of the cases in 1992. Amebiasis and shigellosis each had less than 1 percent of all of the cases in 1992. The overall pattern in table 3 is one of stability, with the majority of foodborne illness with HIV mentions falling into the generic category of unspecified gastroenteritis and colitis. This pattern might be expected, given the complex etiology of foodborne and waterborne illness, especially among persons 25 to 54 years of age.

Table 4 presents data for hospital HDC's with mention of foodborne illness by the type of disease mentioned on the certificate (lines 1–7) for the United States in 1992. This table includes all persons, over 800,000 certificates, who were discharged from hospitals, including the approximately 18,000 certificates with mention of HIV/AIDS infection. Table 4 data provide a comparison of all patients to those patients in table 3. Two major patterns are clear. First, the pattern of diseases for all patients falls into 14 categories of ICD–9 disease codes, while HIV/AIDS patients fall into only 9 of the ICD–9 disease codes. Missing are cases of cholera, typhoid, food poisoning, cysticorsosis, and noxious substances eaten as food. Secondly, the category of unspecified gastroenteritis

Table 3—Hospital discharge certificates, mention of foodborne illness with HIV/AIDS infection, by type of disease, United States, 1988–92

Foodborne disease (ICD–9 code)	1992	1991	1990	1989	1988
	Percent distribution of foodborne disease by year of discharge				
Salmonella infection (003.0–003.9)	2.5	2.1	2.6	1.7	4.1
Shigellosis (004.0–00.49)	0.6	1.1	0	0.2	0
Amebiasis (006.0–006.9)	0.2	0.2	0	0	0.3
Protozoal intestinal disease (007.0–007.9)	7.1	11.6	12.0	9.1	9.1
Intestinal infections due to other organisms (008.0–008.8)	16.6	19.6	15.1	23.5	13.6
Ill-defined intestinal infections (009.0–009.3)	7.1	7.9	12.1	8.6	22.7
Listeriosis (027.0)	0	0	0	0.7	0
Viral hepatitis A (070.0, 070.1, 070.9)	1.2	5.8	4.1	3.4	1.1
Unspecified gastroenteritis and colitis (558.9)	64.7	51.7	54.1	52.8	49.1
Number of mentions	17,960	17,855	13,715	9,434	9,546

Note: The number of mentions by year may differ from those in other tables because some sample observations have multiple mentions of foodborne illness.
Source: USDHHS CDC, National Hospital Discharge Survey.

Table 4—Hospital discharge certificates, mention of foodborne illness by type of disease, United States, 1992

Foodborne disease (ICD–9 code)	Mentions of foodborne illness	
	Number	*Percent*
Cholera (001)	251	0.03
Typhoid (002)	713	0.09
Salmonella (003)	10,296	1.25
Shigellosis (004)	3,219	0.39
Other food poisoning (005)	3,753	0.46
Amebiasis (006)	1,334	0.16
Other protozoal intestinal disease (007)	3,616	0.44
Intestinal infection due to other organisms (008)	209,114	25.48
Ill-defined intestinal infection (009)	30,885	3.76
Listeriosis (027)	914	0.11
Viral hepatitis A (070, .1, .9)	8,685	1.06
Cysticercosis (123.1)	963	0.12
Trichinosis (124)	0	0
Unspecified gastroenteritis and colitis (558.9)	544,180	66.3
Noxious substances (988)	2,876	0.35
All mentions	820,799	100

Note: The total number of mentions differs from those in other tables because some sample observations have multiple mentions of foodborne illness. Mentions are counted on lines 1–7 on the discharge certificate.
Source: USDHHS CDC, National Hospital Discharge Survey.

and colitis (ICD–9 Code 558.9) dominates all cases (66.3 percent) as well as HIV/AIDS cases (64.7 percent). Intestinal infections due to other organisms (ICD–9 Code 008) ranked second in both table 3 (at 16.6 percent) and table 4 (at 25.5 percent). Mention of protozoal intestinal disease (ICD–9 Code 007) is consistently higher (over 7 percent) for HIV/AIDS patients than for all patients combined (about 0.4 percent of all mentions).

Evaluation of Findings

The findings contained in this report are based on the NHDS and are subject to the limitations of any large sample survey. An evaluation of the accuracy and reliability of the survey is being done and will assist in the interpretation of the trends discussed here. The point is that even within the universe of HDC's, there is a possibility for error in sampling procedures, recording certificate data, correctness of data entered, and other problem areas. However, the data from this survey at the national level have the important advantage of providing an unobtrusive and noninvasive source of statistics on socially sensitive health problems, even though it is not error-free.

Beyond the problems associated with the discharge certificate data set itself, there are other considerations that cause the estimates of foodborne illness, HIV/AIDS infection, and foodborne illness with mention of HIV/AIDS infection discussed in this report to be lower than the actual levels in the population of the United States. In the first instance, there is uncertainty concerning which ICD–9–CM codes are diseases that are foodborne or

waterborne. The bacterial, viral, and parasitic agents of infection may be clearly identified, but the placement of the resulting diagnosed disease for each patient is more problematic. It is important because it is the link between the disease and other characteristics of the patient that make demographic analysis possible. The actual level of foodborne illness is underestimated to the extent that ICD–9 codes are not included when they should be, at least in part. In addition, it is suggested that ICD–9 codes should be more detailed to include disease-specific studies and be flexible enough to accommodate the discovery of new agents in the future (Helmick et al., 1994). The next revision should attempt to overcome some of these shortcomings.

The hospital discharge data are an underestimate because not all cases of foodborne illness and HIV/AIDS infections result in hospitalization. Many patients are treated by private physicians as ambulatory care patients and do not become part of the discharge certificate survey. The National Ambulatory Medical Care Survey of 1990 recorded over 6 million physician office visits in which the patient was diagnosed with foodborne illness, using the same working definition as in this report. This is compared to the approximately 800,000 HDC's with mention of foodborne illness in 1990. If age-specific patterns were examined, the difference between the two data sources would be even more marked. This significant difference is one reason the present report did not base the rates on the general population, as is typically expected.

In addition to the patients receiving ambulatory care from private physicians, there is an important segment of the population who suffer from foodborne illness who do not seek medical attention but rather advice from friends, relatives, and family members (Vargas, 1990; Swedlund and Armelagos, 1990; Wolinsky et al., 1989). Likewise, the number of persons in the United States who have the HIV/AIDS infection but have not been tested and are not aware of their condition is unknown. This segment of the population may involve more people than all of the combined ambulatory patients and hospital discharge patients in a given year. Special sample survey data are required to estimate the magnitude of foodborne illness cases and HIV/AIDS infections that are now unreported in the official statistics.

All of the data sets discussed above are retrospective in the sense that foodborne illness or HIV/AIDS infection must have already occurred in order for the event to be recorded. A separate problem is faced when prospective studies are required to predict future trends in foodborne illness, HIV/AIDS infections, and the relationship between the two. High-risk population groups need to be identified in terms of their demographic composition and high-risk behavior. These patterns might then be projected into the future to anticipate demands on the health care system and to enable ameliorative action to reduce the levels of illness of this type. The data needs for this problem are basically different than for retrospective analysis and would add a needed dimension to the study of high-risk groups.

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Identifying Frequent Consumers of Foods Associated with Foodborne Pathogens

Katherine Ralston

Economic Research Service, U.S. Department of Agriculture

Introduction

Identifying subpopulations at high risk of foodborne illness is important for targeting and developing consumer education to reduce risks. Such research is also useful in determining possible niche markets for safer foods. Research to date has identified several groups at greater risk of foodborne illness due to conditions affecting immune system function or pathogen exposure, described in table 1. Individuals at high risk because of lower immune function include young children, the elderly, pregnant women, cancer patients undergoing radiation or chemotherapy, organ transplant patients taking immunosuppressant drugs, AIDS patients, and others. Frequent consumers of foods associated with foodborne pathogens are also at higher risk because they are more likely to encounter a food portion with sufficient pathogens to cause illness.

The importance of consumption frequency as a risk factor has been demonstrated in several studies of foodborne illness. Harris et al. (1986) identify more frequent consumption of chicken, game hen, turkey, and shellfish as positively correlated with episodes of *Campylobacter jejuni/coli*. A recent report by the Centers for Epidemiology and Animal Health (1994) lists consumption frequency of ground beef as a risk factor for illness from *Escherichia coli* O157:H7. Thus, frequent consumers of foods associated with foodborne pathogens represent a target for consumer education, as well as a potential market for safer foods.

Estimates of consumption frequencies for several demographic groups can be used to identify demographic characteristics of frequent consumers of foods associated with foodborne pathogens. Estimates of consumption frequency are also needed for pathogen exposure projections, since pathogen exposure depends on both the prevalence of pathogens in foods and on the frequency of consumption of foods. Pathogen exposure projections are essential for estimating the risk-reduction benefits and cost-benefit ratios of changes in technology and policy (National Research Council, 1983).

This study discusses the merits of several food consumption data bases for use in estimating consumption frequencies of foods associated with foodborne pathogens.

To illustrate consumption differences among demographic groups, average daily consumption probabilities are estimated based on the Continuing Survey of Food Intake by Individuals (CSFII) for gender, regional, ethnic, and income groups. Average daily consumption probabilities for young children, the elderly, and pregnant women are also estimated. These groups are already at risk because of lowered immune system function, and are thus clear targets for consumer education and potential markets for safer foods.

The following sections describe the consumption data requirements for identifying frequent consumers of foods associated with foodborne pathogens, the characteristics of several large dietary intake surveys, and several illustrations of consumption frequencies estimated from the CSFII. The concluding section discusses recommendations for choosing among surveys and estimating daily consumption probabilities.

Data Needed for Identifying Frequent Consumers of Higher Risk Foods

Individual dietary data can be used to estimate the probability of consuming a given food. Consumption probabilities can be estimated for different subgroups to determine whether some groups may be at higher risk due to higher pathogen exposure. The estimated consumption probabilities can also be used in models of foodborne illness to quantify these risk differences. The next three sections discuss the implications of risk modeling for data requirements.

Modeling the Consumer's Risk of Foodborne Illness

Carriquiry's model of risk from foodborne illness (Carriquiry et al., 1990) expresses the probability of illness on a randomly chosen day as a function of the probability that an individual consumes a given number of servings of a food that day and the probability that the food is contaminated above the level required to produce illness. The model focuses on acute risk of foodborne illness that could result from consuming a deleterious number of pathogens during a single day. This focus distinguishes the model from models of chronic risk resulting from long-term exposure to a harmful substance.

Table 1—Factors increasing the risk of foodborne infection or the severity of illness

Factors	Reasons
Microbial	
Type and strain of pathogen ingested	Some pathogens and strains are more virulent than others
Quantity of pathogens ingested	Higher numbers ingested may increase severity of illness, probability of illness, and/or shorten onset time
Host-related	
Age less than 5 years	Lack of developed immune systems, smaller infective dose-by-weight required
Age greater than 50 or 60 years (depending on pathogen)	Immune systems failing, weakened by chronic ailments, occurring as early as 50 to 60 years of age
Pregnancy	Altered immunity during pregnancy (fetus usually at greater risk than mother)
Hospitalized persons	Immune systems weakened by other diseases or injuries, or at risk of exposure to antibiotic-resistant strains
Concomitant infections	Overloaded or damaged immune systems
Consumption of antibiotics	Alteration of normal intestinal microflora
Excessive iron in blood	Iron in blood serves as nutrient for certain organisms
Reduced liver/kidney function (alcoholism)	Reduced digestion capabilities, altered blood-iron concentrations
Possession of certain human antigenic determinants duplicated or easily mimicked by microorganisms	Predisposition to chronic illnesses (sequelae)
Surgical removal of portions of stomach or intestines	Reduction in normal defensive systems against infection
Immunocompromised individuals including those on chemotherapy or radiation therapy; recipients of organ transplants taking immunocompromising drugs; persons with leukemia, AIDS, or other illnesses	Immune system inadequate to prevent infection Increased likelihood of ingesting pathogens
Stress	Body metabolism changes allowing easier establishment of pathogens, or lower dose of toxin required for illness
Poor hygiene	Increased likelihood of ingesting pathogens
Diet-related	
Frequent consumption of high-risk foods, such as raw or rare animal products	Increases the probability of ingesting infectious doses of pathogens
Ingestion of fatty foods (such as chocolate, cheese, hamburger) containing pathogens	The fat protects pathogens against stomach acids
Nutrition deficiencies either through poor absorption of food (mostly ill or elderly persons) or unavailability of adequate food supply (starving persons)	Inadequate strength to build up resistance and/or consumption of poor-quality food ingredients that may contain pathogens
Consumption of antacids	Decreased acidity of stomach; reduced effectiveness of hydrochloric acid in stomach
Consumption of large volume of liquids, including water	Dilution of acids in the stomach and rapid transit through the stomach
Other	
Geographic location	Likelihood of exposure to endemic virulent strains, limited food and water supply, market channels limiting dispersion of foods, varied distribution of organisms in water and soil

Source: Adapted from Council for Agricultural Science and Technology, 1994.

Because very small amounts of a contaminated food can produce illness, the model is based on the number of servings rather than the total amount consumed.[1] Thus, data on number of portions, rather than the weight of consumption, would be sufficient for use in this type of model. If multiple portions of a food have completely dependent contamination probabilities, so that all portions consumed that day are either contaminated or not, then the probability that the individual becomes ill is simply the probability that the individual consumes one or more portions multiplied by the probability that the original source of the portions is contaminated. This would apply to hamburgers, for example, if multiple portions are prepared at home from a package of ground beef that is either contaminated or not. For such foods, dietary data can be used to estimate the probability of consuming "one or more servings" for use in Carriquiry's model. Consumption probabilities can be estimated as the observed frequencies, the percent of individuals reporting consumption of each food.

Some foods are more likely to have independent contamination probabilities. This would be true, for example, for hamburgers consumed away from home, but not purchased at the same place. Even if the probability of contamination is the same, the contamination of a portion from one source does not affect the probability of contamination at another source. Then the risk of illness will depend on the probabilities of consuming one portion, two portions, and so on. If each portion's contamination probability is C, the risk that a random individual consuming X portions becomes ill is $1 - (1 - C)^X$. A randomly chosen individual's probability of illness on a random day is then:

$$\text{Prob (1 portion)} \times C$$
$$+ \quad \text{Prob (2 portions)} \times (1 - (1 - C)^2)$$
$$+ \quad \text{Prob (3 portions)} \times (1 - (1 - C)^3)$$
$$+ \quad \ldots$$

For these foods, dietary data would be used to estimate the daily probability of consuming one portion, two portions, and so on. These probabilities would be estimated from dietary data as the percent of individuals consuming each number of portions during a day.

Variables Needed

The ideal data base for examining consumption of foods associated with foodborne pathogens would include codes for the following foods:

- Raw hamburger/ground beef

- Rare hamburger/ground beef (still pink inside)

- Raw oysters, clams, mussels

- Lightly cooked chicken or turkey (not cooked until juices run clear)

- Lightly cooked eggs (running yellow or white parts)

- Raw fish

- Uncooked foods containing raw eggs (Caesar salad, Hollandaise sauce, homemade ice cream, mayonnaise, meringue)

- Raw unpasteurized milk

To answer the question, "How and where can individuals consuming high-risk foods be reached?" information on both the consumer and the foods themselves could be useful, including:

- Gender

- Income

- Education

- Marital status

- Geography

- Ethnicity

- Urban/rural orientation

- Employment

- Frequency of away-from-home consumption

- Where high-risk foods are prepared and consumed (home/away from home)

- Food preparation and handling practices

To estimate exposure for individuals already at risk because of other factors, it would be useful to have information on other risk factors, such as:

- Age (under 5 and over 65)

- Pregnancy status

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[1] This discussion relies on the assumption that pathogens are distributed evenly throughout the food. The model can be defined to account for uneven distribution of pathogens.

- Conditions compromising immune system function, such as cancer, AIDS, organ transplant

Data Dimensions

Carriquiry's model requires only 1 day of consumption data per individual to assess the probability that a randomly chosen individual will experience an illness episode on a given day. For estimates of average probabilities for the whole population or for subpopulations, the intraindividual variation in consumption can be ignored, and additional days of data per individual may be pooled. To estimate the number of individuals falling above some risk threshold, it would also be useful to examine the distribution of "usual probabilities" among individuals, using additional days of data to account for intraindividual variation. A large number of person-days is desirable to estimate the daily consumption probability of infrequently consumed foods, such as raw shellfish.

Surveys with Individual Dietary Data

Available dietary intake surveys with demographic information and large sample sizes include:

- The National Health and Nutrition Examination Survey III (NHANES III) conducted by the National Center for Health Statistics (Centers for Disease Control and Prevention, U.S. Department of Health and Human Services)

- The Continuing Survey of Food Intake by Individuals II (CSFII II) conducted by the U.S. Department of Agriculture's (USDA's) Human Nutrition Information Service (now Agricultural Research Service)

- The Market Research Corporation of America Panel Diary Survey

- The National Purchase Diary Group, Inc., National Eating Trends Survey

None of the surveys can distinguish rare hamburger or undercooked poultry. While there are surveys covering general practices, estimates of consumption frequency are much more useful for use in risk assessment models. For example, a 1994 survey conducted jointly by the Food and Drug Administration (FDA) and the USDA suggests that 25 percent of households usually serve hamburgers "rare" or "still pink in the middle" (USDA FSIS, 1994). Consumers who prefer rare hamburgers may consume hamburgers much more or less frequently than other consumers, however. Thus, while 25 percent of consumers serve hamburgers lightly cooked, the fraction of

all hamburgers served lightly cooked may be much greater or less than 25 percent. The frequency of consumption of lightly cooked foods is much more accurately estimated by a consumption recall or daily food diary survey with the appropriate codes to distinguish these foods.

All of the surveys can distinguish raw eggs, raw ground beef, and several types of raw fish. The NHANES has an additional code to distinguish homemade foods with raw eggs, such as ice cream, hollandaise sauce, and Caesar dressing. While lightly cooked eggs are not distinguished by the food code, they may represent a large fraction of fried and poached eggs, since this includes any eggs with liquid yolk.

Each survey has some individual advantages and disadvantages, as discussed below.

Continuing Survey of Food Intake by Individuals

The CSFII 1989–91 provides data on roughly 15,000 individuals with 3 days of dietary recall. The data set for 1989 and 1990 includes roughly 10,000 individuals and 23,000 pooled person-days of data. Data for 1991 were released too late for inclusion in this review.

The sample was drawn as a complex multistage sample of individuals living in residential households. A separate sample was drawn for low-income households to allow over-sampling for this group. The total sample covers the 48 contiguous States. Sixty-three percent of occupied housing units in the basic sample agreed to participate, and 82 percent of occupied and eligible households in the low-income sample participated. For both samples, 73 percent of participating individuals completed 3 days of food records. The 1990 response rates were slightly lower: 62 percent of households in occupied units in the basic sample agreed to participate, and 81 percent of low-income sample eligible households participated. Of individuals in participating households, those completing 3 days of food records were 63 percent of the basic sample and 60 percent of the low-income samples.

While the survey provides multiple days of consumption data, data quality is generally believed to decline with each increasing day of the survey. This raises not only the problem of incomplete recall, but of inconsistent recall across days. This may be less of a problem for the foods most important in foodborne illness, which include meats, milk, and eggs. Meats and eggs consumed as main dishes may be relatively easily recalled; milk may also be easily recalled if it is habitually consumed as a snack or always with certain meals. Further, for acute risk models, the portion size is not as important as the frequency of

consumption. Sauces, salad dressings, desserts, or beverages containing uncooked eggs may be less easily recalled, however.

The survey includes some questions on food safety knowledge and practices, such as avoiding rare meat. The survey also includes detailed data on the source of foods, even when they are consumed at home. This would be useful in combination with contamination rates for foods from fast-food establishments.

National Health and Nutrition Examination Survey

NHANES III Phase I (1988–91) also includes a dietary recall for 14,000 individuals. The dietary recall covers only 1 day per individual, which is sufficient for an estimate of the daily risk of illness.

This survey is a stratified multistage design. The sample oversamples children under 5 and adults over 60. These groups have been clearly identified as more vulnerable to foodborne illness, and identifying high-risk consumers within these groups is facilitated by this over-sampling. The sample also oversamples African-Americans and Mexican-Americans, which will improve dietary estimates for these groups as well. African-Americans may be at slightly greater than average risk of death from foodborne illness, based on evidence from the National Hospital Discharge Survey (NHDS) (Steahr, 1994).

The response rate for sampled individuals completing 1 day's dietary recall was 73 percent. NHANES does not distinguish many foods purchased away from home but consumed at home. It does, however, distinguish several foods from fast-food establishments with separate codes. Further, it identifies several foods as homemade, such as ice cream, hollandaise sauce, and Caesar dressing, which are made with raw eggs.

The survey includes medical information that could be used to examine the diets of individuals with higher risk factors. For example, the survey would allow an estimate of the frequency of high-risk foods among individuals who have been ever diagnosed with cancer and may be immunocompromised.

Menu Census Survey

The Market Research Corporation of America (MRCA) conducts the Menu Census Survey, an ongoing survey covering about 6,000 individuals per year for 14 consecutive days. This represents a much larger potential number of pooled person-days (84,000), and because the survey is ongoing, multiple years could be combined for a very large sample. This would be useful to reduce the relative

variance of estimates of low frequency events, such as consumption of raw oysters. The large sample size would also allow estimates for demographic breakdowns.

Households are recruited for the survey from a larger survey conducted by MRCA. Both the larger survey and the sample drawn for the Menu Census Survey are stratified to 456 geographic and demographic cells. The larger survey sample is drawn from automobile registration lists and other lists for targeting households to match demographic characteristics. The participation rate for the larger survey is considered proprietary information, although MRCA can provide information to evaluate how representative the sample is. A subsample of households who participate in the larger survey are asked to participate in the Menu Census Survey. In 1994, 60 percent of sampled households elected to participate, and 92 percent of those completed at least 11 days of diaries. Sample selection bias may result from the double sampling process because households that are willing to participate in both the larger survey and the Menu Census Survey may differ in some ways from the general population, even though demographic characteristics of the sample are representative.

The large number of days per individual, while useful for sample size, could present problems of declining recall quality as the survey progresses, although respondent training and compensation may minimize these problems.

The Menu Census Survey does identify foods that are consumed raw, but it does not distinguish foods that are consumed rare or lightly cooked. MRCA can add custom questions for additional funding.

National Eating Trends

The National Purchase Diary Group, Inc., conducts food consumption surveys covering 2,000 households (roughly 5,100 individuals) for 14 consecutive days. For the past 2 years, however, foods purchased and consumed away from home have not been coded. This leaves out a large fraction of high-risk food consumption.

Consumption Probability Illustrations

Consumption probabilities for several foods and several population groups were estimated using the CSFII data for 1989–90, the only data set already publicly available.[2] Each group's average daily probability of consuming a food is estimated here as the daily proportion of the group reporting consumption of the food, averaged over

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[2]Data for 1991 were released too late for inclusion in this paper.

3 days. In practice, this is simply the percent of person-days reporting consumption, where 3 days of food records for each individual are pooled. Pooling of person-days is acceptable for estimates of probabilities for the whole population or for subpopulations. To examine the distribution of probabilities among individuals, a "usual probability" could be estimated using multiple days of data to account for intraindividual variations.

Estimates combine the basic sample and low-income sample of the CSFII, using weighting factors to correct for oversampling. Only individuals who completed 3 days of records are included in the estimates. This results in a sample size of 7,816 individuals in the combined 1989–90 survey.

The probability of consuming "one or more portions" of a food is illustrated here, rather than the individual probabilities of consuming specific numbers of servings. The probability of consuming "one or more portions" can be used in Carriquiry's model if multiple portions of the food come from a single unit that either is or is not contaminated. For foods with independent contamination probabilities of multiple portions, using the consumption probability of "one or more portions" will underestimate the risk of illness. For such foods, the probabilities of consuming one portion, two portions, and so on, must be estimated separately. Further research is needed to determine whether contamination probabilities are independent for different foods and for foods from different sources, such as home and away from home.

Raw Foods

CSFII identifies several raw foods that are associated with risk of foodborne illness. For the illustrations here, they are grouped into four categories:

- Raw beef (raw ground beef, steak tartare, and raw liver)

- Raw fish (unspecified, flounder, herring, mackerel, mullet, ocean perch, pompano, porgy, salmon, tuna, and squid)

- Raw shellfish (clams, mussels, and oysters)

- Raw eggs (raw whole egg, raw egg yolk, and raw egg white)

The percent of person-days consuming these raw foods is given in table 2. Among consumers who completed 3 days of records, there were no reports of raw beef consumption. This illustrates the problem of estimating probabilities for rare events: anything but a very large

sample may fail to include even a single consumer. Estimated daily consumption probabilities for the other raw foods are 0.04 percent for raw fish, 0.09 percent for raw shellfish, and 0.09 percent for raw eggs. All of these foods were reported consumed by less than 10 individuals out of 7,800 who completed all 3 days of intake data, and are thus subject to large relative variances.[3]

For events this infrequent, the sample size of the CSFII for 2 years (1989–90) is too low for an acceptable frequency estimate, or for any disaggregation. The additional data from 1991 would not sufficiently increase the sample size. The NHANES (1988–91) sample, which includes only 1 day of data, is likewise too small to estimate frequencies for these foods. The MRCA Menu Census Survey data, with 14 days per individual and the potential for multiple years of pooling, would be more appropriate for these estimates.

Chicken, Ground Beef, Shellfish, and Eggs

While none of the large dietary surveys identifies rare foods such as chicken and hamburger, they can all be used to estimate the probability of consumption for several categories of foods associated generally with foodborne illness. This is still useful, since several studies have shown that consumption of certain foods, such as chicken, ground beef, and shellfish, increases the risk of foodborne illness, even without further information on the cooking technique used (Harris et al., 1986; Centers for Epidemiology and Animal Health, 1994). Consumption

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[3]Some instances of raw food consumption may be missed because consumers are not probed to specify whether the food is raw. The Economic Research Service has recommended to the Agricultural Research Service that future surveys include probes to improve identification of raw foods, as well as rare or lightly cooked foods, which currently are not identified at all.

Table 2—Estimated consumption probabilities for raw foods, U.S. average, 1989–90

Food	Estimated consumption frequency
	Percent of person-days
Raw beef	0
Raw fish	0.04
Raw shellfish	0.09
Raw eggs[1]	0.09

[1]Raw egg consumption here includes only that reported directly by the respondent and does not include raw eggs as an ingredient in salad dressing, mayonnaise, or sauces.
Source: USDA ARS, 1989; USDA ARS, 1990.

probabilities can also be estimated for eggs; codes available in the CSFII make it possible to focus on higher risk forms, such as fried and poached eggs, which are often consumed with liquid yolks.

Average daily consumption probabilities were estimated for four categories of foods easily identifiable from all the large dietary surveys: chicken, ground beef, shellfish, and eggs. Chicken, ground beef, and shellfish categories include both raw and cooked forms, with no additional information about cooking. The egg category includes raw, fried, and poached eggs. Estimated U.S. average probabilities for these foods are 17.6 percent for chicken, 15.5 percent for ground beef, 1.8 percent for shellfish, and 8.8 percent for raw, fried, or poached eggs. Tables 3, 4, 5, and 6 compare estimated consumption probabilities across age–gender, regional, ethnic, and income divisions. Table 7 illustrates consumption probability estimates for some groups who are at higher risk of foodborne illness because of less effective immune system functions.

Age–Gender Variation

Consumption probabilities for males and females are very similar for chicken both for teenagers and older adults, at 16–17 percent of person-days for teenagers, and 18 percent for adults. Beef, shellfish, and raw or lightly cooked egg consumption probabilities are higher for males in both age groups. Male teenagers consume ground beef on 27.1 percent of person-days, compared to 20.7 percent for females. Male adults over age 20 consume ground beef on 16.5 percent of person-days compared to 12.5 percent for females. Male teenagers consume shellfish on 1.4 percent of person-days compared to 0.32 percent for females, and males over 20 consume shellfish on 2.7 percent compared to 1.8 percent for females over age 20. Consumption of raw, fried, or poached eggs is estimated at 8.6 percent of person-days for male teen-agers, compared to 6.9 percent for females. Male adults over age 20 consume raw, fried, or poached eggs on 12.2 percent of person-days compared to 7.4 percent for females. The estimates also suggest that chicken and shellfish probabilities are higher for both adults over 20 than for teenagers, while ground beef and egg consumption probabilities are higher for teenagers than adults over 20 for both males and females.

These estimates illustrate the substantial differences in consumption patterns among age-gender groups, which could be important for targeting consumer education and identifying markets for safer foods.

Regional Differences

Northeastern consumers report the highest percentage consuming chicken (21 percent of person-days), while consumers in the South consume nearly 20 percent. The West and North-Central regions report about 14 percent of person-days consuming chicken. Regional differences in ground beef consumption are somewhat less than for chicken. While the national average probability is 15.5 percent of person-days, the lowest estimated probability is for the Northeast at 12.7 percent, and the highest is for the South at 16.8 percent. While the probability of shellfish consumption is low, regional

Table 3—Estimated consumption probabilities for chicken, ground beef, shellfish, and eggs, by age and gender, 1989–90

	Chicken	Ground beef[1]	Shell-fish	Eggs[2]
	Percent of person-days reporting consumption			
U.S. population	17.6	15.5	1.8	8.8
Males	16.8	27.1	1.4	8.6
Females	16.3	20.7	0.3	6.9
Males 20+	18.0	16.5	2.7	12.2
Females 20+	18.3	12.5	1.8	7.4

[1]Ground beef includes ground beef patties, hamburgers, cheese-burgers, and other ground beef patty sandwiches.
[2]Eggs includes whole raw eggs, raw yolks, raw whites, fried eggs, and poached eggs.
Source: USDA ARS, 1989; USDA ARS, 1990.

Table 4—Estimated consumption probabilities for chicken, ground beef, shellfish, and eggs, by region, 1989–90

	Chicken	Ground beef[1]	Shell-fish	Eggs[2]
	Percent of person-days reporting consumption			
United States	17.6	15.5	1.8	8.8
Northeast	21.3	12.7	1.0	6.7
North-Central	4.3	15.9	1.0	7.8
South	19.8	16.8	1.6	7.1
West	14.4	15.4	2.3	14.8

[1]Ground beef includes ground beef patties, hamburgers, cheese-burgers, and other ground beef patty sandwiches.
[2]Eggs includes whole raw eggs, raw yolks, raw whites, fried eggs, and poached eggs.
Source: USDA ARS, 1989; USDA ARS, 1990.

Table 5—Estimated consumption probabilities for chicken, ground beef, shellfish, and eggs, by ethnic group, 1989–90

	Chicken	Ground beef[1]	Shell-fish	Eggs[2]
	Percent of person-days reporting consumption			
U.S. population	17.6	15.5	1.8	8.8
Hispanic-Americans	22.5	16.0	1.3	15.7
European-Americans	15.7	15.4	1.7	7.8
African-Americans	26.2	17.3	2.4	9.4
Others	20.4	6.6	2.3	16.3

[1]Ground beef includes ground beef patties, hamburgers, cheeseburgers, and other ground beef patty sandwiches.
[2]Eggs includes whole raw eggs, raw yolks, raw whites, fried eggs, and poached eggs.
Source: USDA ARS, 1989; USDA ARS, 1990.

Table 6—Estimated consumption probabilities for chicken, ground beef, shellfish, and eggs, U.S. average and low-income average, 1989–90

	Chicken	Ground beef[1]	Shell-fish	Eggs[2]
	Percent of person-days reporting consumption			
U.S. population	17.6	15.5	1.8	8.8
Low-income	17.9	15.4	0.9	12.4

[1]Ground beef includes ground beef patties, hamburgers, cheeseburgers, and other ground beef patty sandwiches.
[2]Eggs includes whole raw eggs, raw yolks, raw whites, fried eggs, and poached eggs.
Source: USDA ARS, 1989; USDA ARS, 1990.

variation is high. The Northeast reports the highest consumption rate at 2.5 percent of person-days, while the North-Central region reports only 1 percent. The U.S. average is 1.8 percent. Regional variation is also high for consumption of raw, fried, or poached eggs. The national average is 8.8 percent of person-days, while the Northeast reports 6.7 percent, and the West reports 14.8 percent.

Table 7—Estimated consumption probabilities for chicken, ground beef, shellfish, and eggs, for U.S. population and selected high-risk groups, 1989–90

	Chicken	Ground beef	Shell-fish	Eggs[2]
	Percent of person-days reporting consumption			
U.S. population	17.6	15.5	1.8	8.8
Under 5	14.3	12.0	0.4	6.2
Over 65	17.0	9.2	1.3	10.6
Pregnant	17.9	11.4	0.6	8.2

[1]Ground beef includes ground beef patties, hamburgers, cheeseburgers, and other ground beef patty sandwiches.
[2]Eggs includes whole raw eggs, raw yolks, raw whites, fried eggs, and poached eggs.
Source: USDA ARS, 1989; USDA ARS, 1990.

Ethnic Variation

Chicken consumption probabilities for all ethnic groups other than European-Americans are higher than the national average. While European-Americans report 15.7 percent of person-days consuming, African-Americans report 26.2 percent, Hispanic-Americans report 22.5 percent, and non-Hispanic others report 20 percent. Ground beef consumption is fairly similar for European-Americans, Hispanic-Americans, and African-Americans, at 16 percent, 15.4 percent, and 17.3 percent, respectively. Others report much lower rates at 6.6 percent. Shellfish consumption is lower than average for Hispanic-Americans at 1.3 percent, while African-Americans and others report higher than average frequencies, at 2.4 and 2.3 percent, respectively. Consumption of raw, fried, and poached eggs is much higher than the U.S. average for Hispanic-Americans and others at 15.7 and 16.3 percent of person-days, respectively, while European-Americans and African-Americans report consumption close to the average at 7.8 and 9.4 percent.

Income Variation

Consumption by low-income consumers is fairly similar to the U.S. average for chicken, at about 17.9 percent of person-days reporting consumption. For ground beef, low-income consumers consume at almost the same rate as the U.S. average. For shellfish, the consumption rate for low-income consumers is only half the national

average at 0.9 percent. For consumption of raw, fried, or poached eggs, the rate is much higher than the U.S. average, at 12.4 percent of person-days.

Consumption Frequency of Other Risk-Factor Groups

Estimated daily consumption probability for children under 5 (table 6) is lower than the U.S. average for all four food categories. Elderly consumers report close to the national average for chicken, lower frequencies for ground beef and shellfish, and a higher frequency for consumption of raw, fried, or poached eggs. Pregnant women report slightly higher frequencies for chicken, somewhat lower frequencies for ground beef and raw, fried, or poached eggs, and a much lower frequency for shellfish at only 0.6 percent.

These estimates are useful in estimating the potential market for safer foods, which could result from educating food preparers for these groups about their increased risks.

Conclusions

For estimating consumption probabilities of high-risk foods without distinguishing cooking techniques, the publicly available dietary data from the CSFII and NHANES have sufficient sample size. The CSFII offers more data points for each individual; this increases the total number of person-days for use in estimates of group averages and could be useful for estimating a "usual probability" distribution. The fact that observations are on consecutive days decreases the usefulness of the additional days of data. Furthermore, the quality of data from the second and third days of the survey is not as high as from the first.

For estimating the lower consumption probabilities of raw foods, the proprietary Menu Census Survey by the MRCA with 14 days of dietary intake records would be more useful, although concerns about possible declining data quality would apply to these data as well.

No large dietary survey currently identifies consumption of rare hamburger and chicken. While surveys on practices do provide some information on rare meat consumption, larger surveys are needed to estimate the frequency in terms of person-days for exposure assessment purposes. The MRCA can add custom survey questions to the Menu Census Survey to cover rare hamburger and lightly cooked chicken. The Economic Research Service has recommended to the Agricultural Research Service that codes to identify these forms of food be added to the next CSFII (1998).

Illustrations of daily consumption probability estimates based on the CSFII 1989–90 show that differences in consumption patterns are, in some cases, large enough to be important in targeting consumer education and in identifying potential niche markets for safer foods. For example, frequent consumers of raw, fried, or poached eggs are males over 20, consumers in the West, and low-income individuals. Individuals over 65, already at greater risk of foodborne illness, also have a higher probability of consuming raw, fried, or poached eggs. This group in particular may represent a clear target for education on food safety. This group may also represent a niche market for safer food forms, such as pasteurized eggs. This analysis of consumption probabilities can be extended by estimating the probabilities of different numbers of portions in a day, as opposed to the probability of consuming once or more. Furthermore, it would be useful to determine which foods are more likely to have independent contamination probabilities for each portion. For example, servings of homemade chicken soup during the same day and exposed to the same storage conditions are likely to have dependent contamination probabilities, while hamburgers consumed away from home at different times during the day are likely to have independent contamination probabilities. Finally, the distribution of individual consumption probabilities could be estimated and combined with some distribution of contamination probabilities to estimate the number of individuals falling above some risk. A demographic profile for those individuals could also be developed to target consumer education more accurately.

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Human Foodborne Disease, Susceptibility, and Food Consumption Data: Comments

Sheila A. Martin
Center for Economics Research, Research Triangle Institute

The three papers presented in this session discuss sources of data for describing and identifying:

- The incidence, severity, and cost of foodborne illness

- Differences in incidence among demographic groups

- Differences in incidence among persons in different risk categories
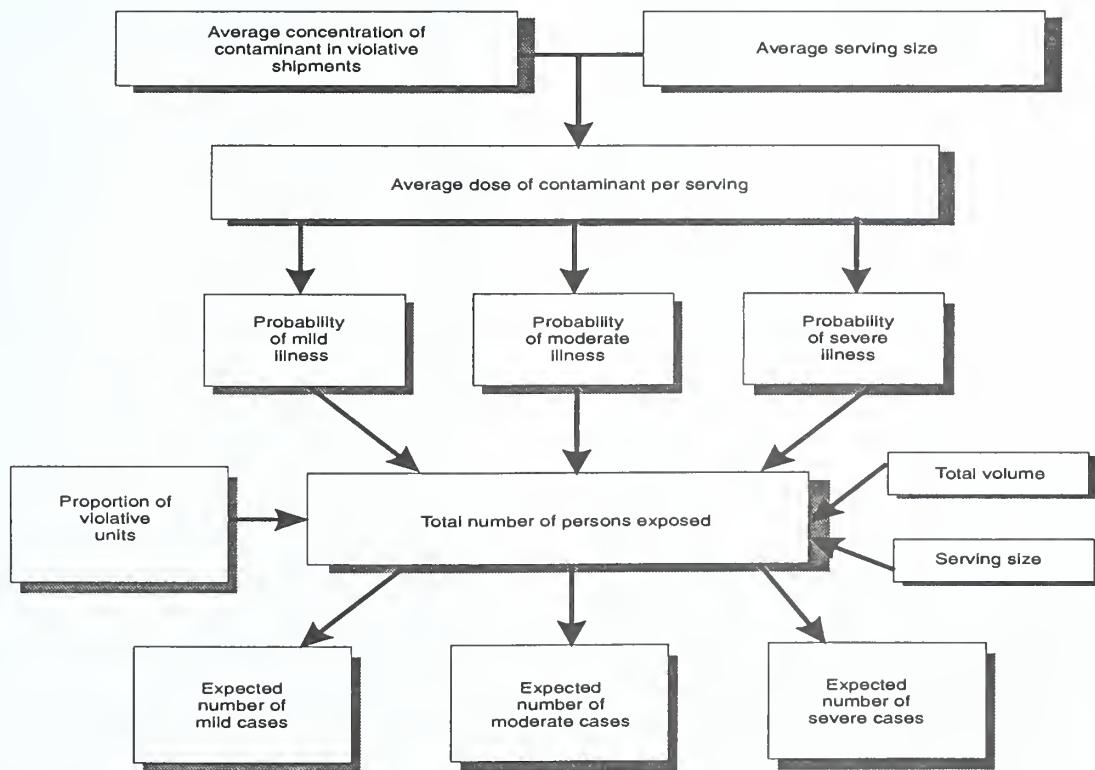
- Factors that affect a person's level of exposure

The usefulness and quality of these data are important because they affect our ability to identify key pathogens, their sources, and possible interventions, and to quantify the effectiveness of interventions. These analyses contribute to our ability to reduce the incidence of foodborne illness.

In each paper, the author describes the data sources available for analysis and identifies the strengths and weaknesses of the data for meeting the analysis objectives. One point made in all of the papers, particularly in the paper by Buzby, is that combining data sources holds the greatest possibility for improving the usefulness of the data for supporting analyses. I would like to emphasize that point by discussing how the data described in these papers might contribute to an integrated analysis and by defining the type of ancillary data that might enrich our understanding of the problem and its solutions.

A number of converging factors result in the risk of foodborne illness. The model shown in figure 1 (Martin et al., 1993) might be used to estimate the expected number of cases of foodborne illness resulting from the contamination of a single food lot. This type of model, when combined with cost data, might be used to measure

Figure 1
Calculations for expected number of foodborne illness cases

the benefits and costs of an intervention. The expected number of cases of illness and their seriousness depend on a number of factors that can be separated into two categories: those that affect the level of exposure; and those that affect the reaction of the receptor, given the level of exposure.

Katherine Ralston's paper discusses factors that affect a person's risk of exposure. Specifically, she examines data concerning people's risk behavior, such as the type of high-risk foods that they eat and the evasive actions they might take, such as thoroughly cooking meat and eggs. This analysis would be enriched by comparing these consumption data to demographic data on the incidence of foodborne illness. For example, although some demographic patterns are found in the consumption of high-risk foods,[1] these patterns are important only if they can be linked to illness incidence. Furthermore, if these data are to be used to formulate and target education campaigns, more information about evasive action is needed. Rather than targeting all who eat hamburger and chicken, it would be more effective to target those who eat rare hamburger or undercooked chicken. In addition, some analysis of the reasons for high-risk behavior, such as culture or information, would be helpful in formulating an education campaign. The National Health Interview Survey may be an appropriate vehicle for collecting this information.

Thomas Steahr addresses the receptor-specific factors that affect reactions to food contamination. He compares the incidence of foodborne illness among people infected with human immunodeficiency virus (HIV) to that of other populations. The goal of his analysis is to identify high-risk individuals so that the medical community can counsel them appropriately.

Dr. Steahr cites some fairly obvious problems with using the National Hospital Discharge Survey for this analysis. For example, the Survey includes only people who sought hospital care for foodborne illness and therefore underestimates the incidence of foodborne illness overall. The other problem he cites is the inadequacy of ICD–9 codes for classifying foodborne illness.

There is at least one other important issue regarding the use of hospital discharge data for this analysis: there may be confounding factors influencing hospitalization. For example, immunocompromised patients and their doctors may be more concerned about the possible effects and complications of foodborne illness and therefore more likely to seek hospital care at the onset of illness. Furthermore, HIV patients may already be under a doctor's care and therefore more likely to seek medical care due to familiarity with the system. An indication of the doctor's reason for hospitalization might help isolate these confounding factors.

One important issue in the analysis of the risk and cost of foodborne illness and of interventions to reduce these risks is the need to combine epidemiological data with biological models of pathogenesis. In treating patients every day, doctors use this process to derive their recommendations for treatment. As shown in figure 1, some method for integrating existing data on foodborne illness into an expert model shows promise for quantifying risks and deriving the benefits and costs of intervention.

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[1]Some of the foods examined in this study are high risk only if evasive action is not taken. For example, ground beef and chicken are high risk only if improperly handled.

Human Foodborne Disease, Susceptibility, and Food Consumption Data: Comments

Fred Kuchler

Economic Research Service, U.S. Department of Agriculture

In the session titled "Human Foodborne Disease, Susceptibility, and Food Consumption Data," presenters showed that some existing data might be useful for examining costs of foodborne illness. Presentations discussed issues of data quality and appropriateness for estimating the extent and severity of foodborne risks. Anne Haddix (see Buzby) reviewed several data sources on diagnosed illnesses, treatments, and outcomes and their components specific to food. Tom Steahr and Katherine Ralston showed that we can make inroads with current data sources to identify the consumer subpopulations most at risk from foodborne illness.

The joint message of the three presentations is that current data on foodborne illness are broad but not very deep. Six data sources are described in Buzby, and the description shows that some are good for estimating productivity losses due to time away from work or premature death. Some are good for estimating medical expenses. These types of data allow the calculation of dollar costs of illness, an area that Tanya Roberts has pursued to great effect. Other data are good for estimating which consumers are at risk. Some allow us to link demographic information with disease incidence and severity. None takes us directly from food consumption levels and concomitant exposure to specific numbers of microorganisms to disease, treatment, and health and cost outcomes.

These data and linkages are necessary for a complete accounting of costs and benefits of Government programs intended to reduce the incidence and severity of foodborne disease. Control programs will probably be directed toward controlling specific pathogens or toxins on particular commodities. Analysts will have to measure disease incidence to measure program effectiveness. Understanding the linkages between control and outcome is important for selecting among control options. Analysts have to understand the linkages to forecast which control will provide the greatest likelihood of reduction in disease.

Tom Steahr's paper is an example for which foodborne illness puts a particular consumer subpopulation especially at risk. Using hospital discharge data, he showed that foodborne illness is disproportionately a problem for those who are immune-compromised. Health problems associated with human immunodeficiency virus (HIV) increased the likelihood of problems with foodborne

disease. In a complementary paper, Katherine Ralston indicated how far analysts can go with current data showing which consumer subpopulations are most at risk because of their food choices. One data source appears quite rich, allowing risky food choices (consumption of raw beef, fish, shellfish, and eggs) to be linked to demographic information. Unfortunately, the sparseness of reports of eating risky foods means that an astronomically expensive survey would be needed to reliably measure the frequency of risky choices.

A common thread in many of the data sets is the use of International Classification of Diseases (ICD) codes to identify the reason individuals sought medical treatment. ICD codes are currently incomplete and provide insufficient detail for analyzing sources of foodborne illness. Steahr showed us how big a problem this is. In his presentation, 50–60 percent of foodborne illnesses recorded were listed as nonspecific gastrointestinal problems. Illnesses were not linked to any specific microorganism or toxin.

The first commentator, Sheila Martin of Research Triangle Institute (RTI), suggested that with some significant modifications, data sources may be combined to yield useful statistics. She argued that surveys need to collect more information on evasive behavior. This will help estimate the level of exposure. Katherine Ralston showed that exposure varies with demographic factors, and that this shows some evasive behavior: one factor influencing food choices is evasive behavior. However, the extent to which evasive behavior is embodied in home food preparation techniques is unknown. Martin argued that using hospital discharge data raises likely selection bias questions, because there are systematic differences in individuals' willingness to seek help and in the discretion with which hospitalization occurs. She suggested that adding the doctor's reason for hospitalization might reduce bias. An altogether different solution could be to follow the RTI lead and convene experts, systematically combining their opinions where data are absent.

Glenn Morris of the U.S. Department of Agriculture's Food Safety and Inspection Service argued that if we want to link disease incidence with levels of contamination, we need sentinel surveillance data. We could use community data to estimate national disease incidence. He maintained that we need to know how disease

incidence changes with control programs. Without that information, we cannot even do a postmortem on programs.

Carolyn Smith de Waal of the Center for Science in the Public Interest argued that most of our data are not very helpful. Reporting is out-of-date in outbreak survey data, and too few States report. Physicians often fail to provide data—they do not always identify foodborne illnesses or their sources. Smith de Waal also indicated the many questions about risk that remain to be answered: What is an infective dose? Where in the marketing chain does the dose increase? What is protective heat treatment? How does cross-contamination occur?

The presentations emphasized problems that analysts have in even crudely estimating costs, whereas questions from the audience indicated an expectation that intervention

policies will be constructed that will balance benefits and costs at the margin. Questioners asked whether voluntary programs are effective in controlling *Salmonella enteritidis*, and whether traceback programs offer any benefits. There were questions about the impacts on foodborne illness of changes brought about by the General Agreement on Tariffs and Trade (GATT) and the North American Free Trade Agreement. Some commented that GATT would not affect domestic food safety because exporting countries would have to meet U.S. standards, and Codex would resolve differences among standards. Counterclaims were made that monitoring is now inadequate and that GATT will lead to additional imports. The World Trade Organization was recognized as a new system, and it was observed that initial problems could be expected. There was a debate about whether irradiation is cost-effective and acceptable to consumers.

Pathogen Identification on the Farm and the Impact of Farm Management Strategies

William D. Hueston
Center for Epidemiology and Animal Health, USDA Animal and Plant Health Inspection Service

Paula J. Fedorka-Cray
National Animal Disease Center, USDA Agricultural Research Service

Introduction

The *Escherichia coli* O157:H7 outbreak in the Pacific Northwest in early 1993 (CDC, 1993a; Bell et al., 1994) catalyzed a shift in public opinion concerning foodborne disease risks. Whereas residues, particularly pesticide residues, previously were perceived to represent the greatest risk for consumers, public opinion shifted to a recognition of microbial contaminants as a greater risk to public health. Media attention and public concern about microbial contamination have continued, bolstered by additional *E. coli* O157:H7 and *Salmonella* outbreaks. The most recent multistate outbreaks were associated with *Salmonella*-contaminated ice cream in October 1994 (CDC, 1994a) and with *E. coli* O157:H7 in sausage in December 1994 (CDC, 1994b).

The shift in public opinion stimulated a public policy change. Secretary of Agriculture Mike Espy visited the Pacific Northwest during his first weeks in office. He assured the parents of affected children and the public that actions would be taken to strengthen the Nation's safeguards against microbial contamination of meat and poultry. Ironically, while surveillance statistics have long documented that microbial contamination is indeed a far greater problem in food than residues (Bean and Griffin, 1990), little applied research has been directed toward identifying cost-effective strategies for reducing microbial contamination. Public health authorities historically have focused on the final preparation stage, arguing that adequate handling and cooling would negate any risk associated with contamination. The public policy change was heralded by Secretary Espy, who stated that food safety is a shared responsibility from the farm to the table, involving the producer, veterinarian, and packer as well as the food service establishment and home preparer.

Recognition of the shared responsibility along the entire farm-to-table continuum has stimulated research on the application of prevention and control methodologies along the entire food chain. One such application is Hazard Analysis/Critical Control Point (HACCP). HACCP is a systematic approach used in food production to ensure food safety (Rhodehamel, 1992). It identifies specific hazard(s) and preventive measures for their control. Seven principles are applied in the development of HACCP plans. They include hazard assessment, critical control point (CCP) identification, and the establishment of critical limits, monitoring procedures, corrective actions, documentation, and verification procedures. Under this system, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to reestablish control in a timely manner to assure that potential hazards are eliminated (Codex draft, 1992). HACCP has been implemented most often in the food production arena.

HACCP principles were developed to identify the critical control points where contaminants may be excluded, reduced, or eliminated. Also, monitoring procedures were included to ensure that exclusion, reduction, and elimination procedures are functional. Consequently, attention has been focused on pathogen identification at the farm level and on identification of "food-safe" farm management strategies, where applicable. This includes implementation of the HACCP system.

The purpose of this paper is to clarify the challenges of identifying pathogens at the farm level and determining the relative impact of specific farm management strategies. Rather than attempting a cursory overview of all potential foodborne pathogens, the paper focuses on two pathogens singled out in "Healthy People 2000" (USDHHS PHS, 1990, pp. 340–343), the national agenda for health improvement by the end of the century: *E. coli* O157:H7 and *Salmonella* species. Furthermore, the paper is limited to a single commodity for each pathogen: *E. coli* O157:H7 in cattle and *Salmonella* in swine. The

choice of these pathogens and commodities is not meant to imply their relative importance but rather to allow a more detailed discussion of the topics at hand, e.g., pathogen identification on the farm and the impact of farm management strategies.

Current Status of *E. coli* O157:H7 in Cattle

The Centers for Disease Control and Prevention characterize *E. coli* O157:H7 as an emerging infection, meeting the definition "infectious diseases whose incidence in humans has increased within the past two decades or threatens to increase in the near future" (CDC, 1993b). First recognized as a human pathogen in 1982, *E. coli* O157:H7 has emerged only recently as a well-known cause of foodborne illness in the United States. While accounting for relatively few cases of foodborne diseases compared to *Salmonella* and *Campylobacter,* individuals infected with *E. coli* O157:H7 have a much greater chance of experiencing serious illness and death. Consumption of beef, principally ground beef, has been associated most frequently with *E. coli* O157:H7 outbreaks, although a wide range of other sources has been documented (USDA APHIS, 1994a).

Experimentally, *E. coli* O157:H7 does not appear to cause disease in cattle (Whipp et al., 1994). Review of clinical records of calves from which *E. coli* O157:H7 was isolated in a large national survey failed to uncover any signs of clinical disease (Wells, 1994). In the field, the organism has been isolated only from feces of live cattle and not from any organ or tissue. Consequently, *E. coli* O157:H7 does not appear to affect health or cause production losses in cattle. Shedding of the organism in the feces allows contamination of the carcass and equipment during slaughter, hence the public health significance.

Controlled experiments where cattle have been exposed to the *E. coli* O157:H7 organism have been used to determine whether cattle actually become infected without disease; whether organ(s) or meat in the live cow become infected; whether cattle shed the organism for a long time, i.e., become carriers; and whether they have any immune response that might allow blood samples to be tested in order to identify affected animals. After experimental inoculation of calves and adults with 10^{10} colony-forming units (CFU) of *E. coli* O157:H7, the organism was confined to the digestive tract (Cray and Moon, 1994). Microscopic examination of sections of intestine were normal, and there was no evidence of the organism spreading to other organs. However, both calves and adults showed a rise in serum antibody titer to *E. coli* O157:H7 lipopolysaccharide, a cell wall component of *E. coli* O157:H7, after inoculation with high doses (Johnson and Cray, 1994).

The life cycle, i.e., ecology, of *E. coli* O157:H7 in nature is unknown. Repeated cultures over time suggest that gut colonization is transient, with a median shedding duration of less than 30 days (Besser and Hancock, 1994). Fecal shedding after experimental inoculation varied widely among animals of the same age group, although calves shed greater numbers and for a longer duration than adults (Cray and Moon, 1994). The likelihood of persistent shedding increased with the size of the inoculum. Individual animals from both age groups shed for months. Two experimentally inoculated calves shed detectable levels of *E. coli* O157:H7 for 20 weeks. Calves that were no longer excreting *E. coli* O157:H7 shed the organism again after reinoculation with the same strain.

Current Status of *Salmonella* in Swine

Salmonella are ubiquitous in nature and have been recovered from nearly all vertebrates (Taylor and McCoy, 1969, p. 3). Over 2,400 species have been identified. More cases of human meat and poultry foodborne disease are attributed to *Salmonella* and *Campylobacter* than any other agent (Menning, 1988). In a study of foodborne disease from 1977 to 1984, Bryan (1988) observed that pork was responsible for 11 percent of the *Salmonella* outbreaks attributed to meat. Bean and Griffin (1990) reported that from 1973 through 1987, pork was the food vehicle for 25 human *Salmonella* outbreaks. A large number of *Salmonella* species (spp.) have been isolated from swine carcasses and pork products (Wilcock and Schwartz, 1992). In one study, Lammerding et al. (1988) recovered *Salmonella* from 17.5 percent of pork carcasses at slaughter. While the impact on the consumer is manifested after consumption of contaminated foods, the problem begins with infected animals on the farm.

Salmonellosis is also a major animal disease problem costing millions of dollars of lost income to the pork industry (Roof et al., 1992; Schwartz, 1991). In swine, *Salmonella choleraesuis* and *Salmonella typhimurium* are most often implicated in swine disease (Wilcock and Schwartz, 1992). They are also the first and third most frequently recovered *Salmonella* serotypes from swine, respectively (Ferris and Thomas, 1993).

Animals that harbor a bacterium that they may or may not shed into the environment are called carriers. Carrier animals are an important component in the epidemiology of *Salmonella*. Swine are known carriers of *Salmonella* spp. (Wilcock and Schwartz, 1992). The source of *S. choleraesuis* seems to be limited to carrier pigs and contaminated facilities, as this serotype is rarely isolated from swine feeds or nonswine reservoirs (Wilcock and Schwartz, 1992). Although *S. typhimurium* is ubiquitous

in the environment, the exact source of disease outbreaks is unknown; however, carrier pigs who shed *Salmonella* are thought to be important in disease dissemination.

Carriers can shed both long-term and short-term. Information regarding development of a carrier state is limited and confined to experimental work or retrospective field observations. Fedorka-Cray et al. (1994) demonstrated that pigs free of *Salmonella* can become infected with and shed *S. typhimurium* within 2 days after exposure to an infected population. However, long-term carriage was not studied. Wood et al. (1989) demonstrated that *S. typhimurium* can persist in low numbers in swine to slaughter weight. Gray et al. (1994a, 1994b) recently determined that development of the carrier state in swine following challenge with *S. choleraesuis* is dose-dependent. Persistence is observed through 15 weeks post-exposure. However, he also demonstrated that following natural exposure to an infected population, the number of pigs developing carrier status was relatively low (Gray et al., 1994c), suggesting differences between experimental and natural exposure.

Pathogen Identification on the Farm

The HACCP principles encourage allocation of prevention and control resources at the most CCP's throughout the food production and preparation process, including the farm. Control at the farm may, in some cases, provide the most cost-effective means of eliminating the pathogens or problems of animal origin. For example, antibiotic residues enter the food chain prior to processing; i.e., during preharvest, when animals are produced, shipped, or marketed. While virtually every producer uses antibiotics, control of residues is amenable to farm-level programs for restricting access to drugs, recording treated animals, and meeting required withdrawal times. However, management science holds that "you can't manage what you can't measure." Therefore, establishing and implementing a HACCP program for microbial pathogens requires pathogen identification and measurement throughout the farm-to-table continuum. The relative importance of farm-level control points for microbiological pathogens depends on (1) the overall prevalence of the pathogen in individual animals and farms, (2) the ease of reduction/elimination of the pathogen, (3) the cost of controls at the farm level, and (4) the sensitivity and specificity of the detection methods.

Few, if any, microbial pathogens can be controlled at the farm level as easily as residues. Nevertheless, evaluating farm-level control options requires knowledge of the distribution of the pathogen(s) in individual animals and production units; i.e., animal prevalence and herd prevalence. In some unique cases, the presence or absence of

the pathogen can be estimated by clinical evaluation of animals alone. An example is "lumpy jaw," a gross enlargement of facial bones associated only with infection by *Actinomyces bovis*. However, in most cases, specific clinical signs such as mastitis, diarrhea, or pneumonia can be associated with any one of several different pathogens. Further complicating pathogen identification on the farm is the fact that some potential foodborne pathogens, such as *E. coli* O157:H7, do not appear to cause any disease in cattle. Therefore, diagnostic tests are required to measure the potential presence of the pathogen.

The scientific method does not allow for proving the negative; e.g., that no organisms exist in a population. Therefore, choice of diagnostic test, sampling design, and sample size are critical components in evaluating the prevalence of potential foodborne pathogens at the farm level.

Diagnostic Tests

Diagnostic tests are performed in the laboratory or the field to identify a particular organism to the exclusion of other related or nonrelated organisms. Identifying pathogens on the farm requires accurate diagnostic tests; however, no known test is perfect. Therefore, studies that identify the presence or absence of specific pathogens must be interpreted cautiously, keeping in mind the limits of the test.

The ideal diagnostic test would have properties that correctly identify all infected animals (sensitivity; type I error) and that also correctly identify all uninfected animals (specificity; type II error). While the ideal is never reached, the optimal method to use in epidemiological investigations is sensitive (misses few infected animals), specific (calls uninfected animals negative), and rapid without compromising accuracy. Where more than one test is available to detect an organism or response to an organism, tradeoffs are made between sensitivity and specificity. The background prevalence of an organism affects the choice of the test. Increased sensitivity is more important in cases of rare diseases, while specificity is more important in high-prevalence diseases. This minimizes false negatives and false positives, respectively. Sensitivity can be increased by testing at multiple times.

Diagnostic tests can be characterized as definitive or presumptive. Definitive tests involve unequivocal identification of the agent, while presumptive tests measure the animals' response to the presumed presence of the agent. Presumptive tests may be misleading due to cross-reactions with other agents. Bacteriologic culture is the method most often accepted as definitive, objective, and sensitive. Isolation of the organism, followed by use of confirmatory tests, such as serotyping or other

biochemical tests, gives the investigator an unequivocal identification. However, all isolation techniques have limits, usually expressed as the minimum detectable number of pathogens identifiable per gram of test material. *E. coli* O157:H7 is diagnosed predominantly by bacteriologic culture of feces, followed by typing for the bacterial surface antigens (USDA APHIS, 1994a). For culture detection of *E. coli* O157:H7, approximately 10^1 to 10^2 CFU/g of sample needs to be present (Thomas and Tucker, 1995). Historically, culture was the most widely used tool for *Salmonella* detection also. With *Salmonella*, detection limits can approach ≤ 10 CFU/g sample (Fedorka-Cray et al., 1994; Cherrington and Huis in't Veld, 1993). In most cases, use of enrichment broths and selective media can enhance sensitivity for both *E. coli* O157:H7 (Sanderson et al., 1994) and *Salmonella* (Bager and Petersen, 1991; Cherrington and Huis in't Veld, 1993), although toxicity has been reported with *Salmonella*. For *Salmonella* isolation, definitive isolation may routinely take up to 5 days (Bager and Petersen, 1991).

The advent of molecular techniques has allowed development of more rapid diagnostic tests, both presumptive and definitive. Use of polymerase chain reaction (PCR) is accepted for the definitive identification of organisms with high specificity. Sensitivity, however, remains the biggest problem associated with PCR (Binns, 1993; Aabo et al., 1993). Typically, use of PCR requires the presence of $> 10^3$ CFU/g of *Salmonella* per sample (Cohen et al., 1994), although use of multiplex PCR may increase the sensitivity to 10^0 CFU if the isolates can be cultured prior to PCR (Way et al., 1993). PCR may also be used to identify nonviable bacterial pathogens (Josephson et al., 1993).

Other molecular techniques involve electrophoresis of genomic DNA. Pulsed-field gel electrophoresis has been used to further characterize the epidemiology of *E. coli* O157:H7 (McAdoo et al., 1994; Pritchett et al., 1994).

Use of immunologic techniques, such as Enzyme Linked Immunosorbent Assay (ELISA), tends to be more presumptive and subjective than other assays, although results may be available more quickly than with definitive tests such as culture. Typically, results can be obtained in 24 hours or less. Their use has been associated most often with detection of bacteria in food samples and sensitivity has been variable (D'Aoust et al., 1990). Use of ELISA in conjunction with bacteriologic culture may equal the sensitivity and specificity of bacteriologic culture (Bager and Petersen, 1991; Cherrington and Huis in't Veld, 1993; D'Aoust et al., 1990). Use of ELISA for serologic analysis may be highly sensitive and specific (van Zijderveld et al., 1992), although field analysis is needed to confirm laboratory findings. ELISA testing for detection of *Salmonella*

carriers in cattle is now being recommended (Konrad et al., 1994).

Measuring the prevalence of a pathogen is not simply a matter of choosing the diagnostic test with the best sensitivity and specificity but also of cost. As an example, at the National Animal Disease Center (NADC) of the U.S. Department of Agriculture's (USDA's) Agricultural Research Service (ARS), supplies for the analysis of one sample for isolation of *Salmonella* spp. cost approximately $3 for bacteriology, $3 to $5 for ELISA, and $12 for PCR. Adding costs for labor (total time to process one sample) pushes the total costs per sample to approximately $15 for bacteriology, $25 for ELISA, and $32 for PCR. Running multiple samples may decrease the cost slightly. Serotyping, for definitive identification of *Salmonella* spp., adds an additional $15 to $25 per sample. Obviously, testing all animals on all farms would be cost-prohibitive.

Sampling Design

Prevalence is an epidemiological term used to describe the occurrence of agents in a population of animals. The prevalence of an agent reflects the proportion of a population from which the agent can be identified in a set period of time. Accurately measuring the prevalence of a specific pathogen requires attention to the sampling design as well as to the diagnostic test.

A census evaluates all of the animals and farms. Due to the expense and logistical difficulties of census approaches, most studies of pathogens on farms involve selecting a sample from the population under study. The design of sample collection from animals and farms determines the population to which the results can be extrapolated. A probability-based sampling design in which each animal and each farm has a known probability of being selected for sampling is required in order to extrapolate to the larger population of interest. Since all animals and farms have an opportunity to participate, these surveys are considered unbiased. Initial studies need to be done to estimate probability.

Most prevalence studies do not involve probability sampling. For example, a traceback of animals and herds associated with a batch of contaminated meat is not a probability sample of the entire national population. Instead, tracebacks may estimate the types of animals or farms from which problems may be encountered. Convenience sampling, such as identification of a group of herds based on their owners' stated willingness to participate, is another nonprobability sampling design. The third most common nonprobability sampling approach is self-selection, such as a situation in which a service is provided to all who come forward.

Self-selection typifies data generated by insurance companies or farm record services. Convenience and self-selection surveys provide prevalence estimates for the sampled population only, unless the sample can be shown to represent a larger reference population without bias.

Generating a national estimate of the prevalence of specific agents requires a probability-based sample. The extrapolation techniques used to translate the sample results to the national prevalence estimate are complex and time-consuming (Dargatz, 1994, pp. 8–24). Since few national probability-based surveys of either pathogens or management strategies exist, preharvest food safety researchers must use these available surveys with caution.

Sample Size

The final component of prevalence estimation relates to the numbers of samples tested. The size of the survey determines the statistical reliability of the resulting prevalence estimates. Furthermore, the likelihood of identifying the agents, if they do exist (e.g., the power), must be considered in interpreting the results. Studies involving small sample sizes and finding no positives must be evaluated cautiously. Because of the lack of power, one cannot say that no positives exist in the entire reference population.

Prevalence Studies of E. coli *O157:H7 in Cattle*

A review of *E. coli* O157:H7 prevalence estimates (table 1) reveals consistent use of definitive microbiological testing but a wide range of sampling designs and sample sizes (USDA APHIS, 1994a). The earliest studies (Wells, 1991) involved tracebacks to the premise of origin of meat involved in a human foodborne disease outbreak. Hancock (1993) followed with convenience sampling of a group of herds in Washington State. The largest study to date involved a USDA Animal and Plant Health Inspection Service (APHIS) National Animal Health Monitoring System (NAHMS) probability-based survey of dairy heifers in herds scattered across 28 States (USDA APHIS, 1993). Additional studies that range from single herd investigations to regional evaluations of herds are underway by USDA, State animal health officials, and university researchers. No census has been undertaken. The studies to date provide similar results indicating that the agent can be identified in many herds, although the number of positive animals appears low at any point in time (Besser and Hancock, 1994). Young, weaned animals are the most likely to be positive.

Longitudinal followup of affected animals revealed transient shedding (Gabber et al., 1994). Therefore, the more animals tested at any single point in time and the more tests conducted over a period of time on a herd of cattle, the greater likelihood that positive animals will be identified.

Unfortunately, the prevalence estimates provided by all of the studies relate to the sampled herds only. No study has examined sufficient cattle of any age group, from either beef, dairy, or feedlot, to generate a statistically sound national estimate. Even though the USDA NAHMS studies are based on a probability sample, one problem that may be encountered is that an insufficient number of samples may be gathered to allow extrapolation to the national herd. In the real world, extrapolation provides an unbiased estimate of the prevalence and requires that a sufficient number of samples be collected for analysis.

Future prevalence studies for *E. coli* O157:H7 in cattle will evolve from (1) outbreak investigations, (2) Government and university research studies, and (3) national animal health monitoring efforts by USDA, principally the NAHMS program. As discussed, each of these will provide a different part of the picture regarding pathogen identification on farms. Outbreak investigations will address immediate public health concerns and generate data that may help predict the risk factors for foodborne disease outbreaks. The research studies, usually involving a small number of intensely monitored herds, will help clarify issues concerning long-term shedders and individual cow risk factors for *E. coli* O157:H7 colonization. National studies, such as NAHMS, hold the best promise for clarifying the overall prevalence of *E. coli* O157:H7 and other pathogens on farms.

Prevalence Studies of Salmonella *in Swine*

Studies of the prevalence of *Salmonella* in swine have been limited to slaughter surveys (Lammerding et al., 1988; Saide-Albornoz et al., 1992) and interviews of farmers regarding their assessment of the cause of health problems observed in their swine (Owen, 1990; USDA APHIS, 1991). While studies may have been initiated recently, to the best of our knowledge there are no published reports of *Salmonella* prevalence in swine on the farm utilizing confirmatory diagnostic tests.

Prevalence studies have been initiated by USDA ARS NADC. Ten farms have been visited to date. Eight have been positive for *Salmonella* and two have been negative. Six of the eight positive farms yielded multiple serotypes (two to five). A total of 10 different serotypes have been recovered from all the farms surveyed, 4 of which have appeared on the list of the top 20 isolates recovered from human sources (Bean and Potter, 1992). From an animal and public health perspective, serotype information is critical to determining prevention and control strategies and for identifying new serotypes that are emerging as disease-producing agents. A national prevalence study of *Salmonella* in swine is planned as part of the USDA APHIS NAHMS 1995 Grower–Finisher survey.

Table 1—Sampling of cattle for E. coli O157:H7 in the United States

Study no./loc. (reference[1])	Period	Animal Number	Animal Type	Site Number	Site Type	Animal prevalence No. Positives	Animal prevalence Percent	Herd prevalence No. Positives	Herd prevalence Percent	Age gp	No./1,000	Comments
1WI (Wells et al., 1991)	1986	226	Dairy cattle	2	Premises	5	2.2	2	100	Calves/heifers Cows	58.8 0.0	Both premises were tracebacks[2]
		428	Dairy cattle	11	Premises	5	1.2	3	27.3	Calves/heifers Cows	25.3 3.7	–
		46	Dairy cattle	1	Stockyard	1	2.2	n.a.	n.a.	Calves/heifers Cows	52.6 0.0	Stockyard was a traceback[2]
2WA/OR (Wells et al., 1991)	1987	539	Dairy cattle	9	Premises	7	1.3	5	55.5	Calves/heifers Cows	22.2 0.0	All premises were tracebacks[2]
		27	Dairy heifers & calves	1	Packing house	0	0.0	n.a.	n.a.	Calves/heifers	0.0	Packing house was a traceback[2]
3a/WA (Hancock et al., 1994b)	1991–92[3]	3,570	Dairy cattle	60	Premises	10	0.3	5	8.3	Calves/heifers Cows	6.5 1.6	All positives found from June–Sept.
3b	1992[3]	1,412	Beef cows	25	Premises	10	0.7	4	16.0	Cows	7.1	Mature, pastured cows
3c	1991–92	600	Feeder cattle	5	Feedlots	2	0.3	2	40.0	Feeders	3.3	–
4a/28 States (USDA APHIS, 1993)	6/91–5/92	6,894	Dairy calves	1,068	Premises	25	0.4	19	1.8	Calves	3.6	No seasonal or regional patterns
4b	1993	303	Dairy calves	14	Positive herds (from study 4a)	12	4.0	7	50.0	Preweaned Postweaned	29.0 53.0	Followup to study 4a
		662	Dairy calves	50	Negative herds (from study 4a)	19	2.9	11	22.0	Preweaned Postweaned	15.0 49.0	Followup to study 4a
5/Ontario Province (Ag. Canada, 1994)	1992–93	1,477	Dairy cattle	80	Premises	12	0.8	8	10.0	Calves Cows	13.5 4.5	Identical isolates in humans support cattle-human transmission
6/WA (Hancock et al., in progress)	1993–94	5,148	Dairy cattle	5	Positive herds (from study 3a)	77	1.5	4	80.0	Preweaned Postweaned Cows	11.5 26.5 6.7	Followup to study 3a (provisional data)
		3,768	Dairy cattle	8	Negative herds (from study 3a)	8	0.2	4	50.0	Preweaned Postweaned Cows	0.0 4.7 0.5	Samples collected monthly for 12 months

n.a. = Not applicable.

– = No comments.

[1] Complete references available upon request from authors (see Conference Participants at end of this volume for contact information).

[2] Premises believed to be potential sources of E. coli O157, based on traceback from human E. coli O157 cases.

[3] Estimated period of sampling; actual period not reported.

Source: USDA APHIS Center for Epidemiology and Animal Health, "Escherichia coli O157:H7—Issues and Ramifications"; and personal correspondence with Dale Hancock and Agriculture Canada officials.

The Impact of Farm Management Strategies

The epidemiological triad comprises agent, host, and environment. The emergence of epidemiology as a scientific discipline attests to the recognition that health and disease are products of interacting forces within this triad. However, understanding the epidemiology of individual agents relative to specific farm management strategies presents a complex problem. Many of the currently accepted relationships between agent prevalence and management strategies have been deduced from careful investigation of one or a small series of farms or a "natural experiment," in which a specific management strategy was observed to coincide with a demonstrable change in agent prevalence. These observations and deductions often are adopted without scientific verification and become embodied in the literature as "generally recognized as effective."

For scientific validation of the impact of farm management strategies, two alternative approaches have been used: (1) observational studies, and (2) experimental studies. Observational studies involve monitoring herds and animals to identify associations between agent prevalence and specific management factors. Observational studies seek to control agent, host, and environmental variables through study design and statistical analyses. The weakness of observational studies is the inability to enumerate or control all variables and the complexity of the statistical analyses. Furthermore, examination of multiple management strategies requires very large numbers of herds in order to control potential confounding factors such as producer experience, differences in climate and geography, or genetic characteristics of the animals.

Observational studies can examine historical records (retrospective), examine the farms at one point in time (cross-sectional), or follow groups of farms over time (longitudinal or cohort). Each type of study has advantages and disadvantages. In the retrospective study, a group of farms on which the pathogen has been identified are compared with another group of farms that are free of the pathogen. The comparison seeks to identify farm management practices unique to the affected or unaffected farms. The cross-sectional studies may include large numbers of farms, like the NAHMS studies, and often serve to generate hypotheses for further intensive evaluation using either observational or experimental research approaches. Lastly, the cohort approach begins by identifying groups of farms that utilize a specific farm management strategy. These groups are monitored over time to track the occurrence of specific pathogens.

Experimental studies seek to physically control all agent, host, and environmental variables except the one under consideration. Experimental studies utilize a wide variety of approaches, from simulated environments in the laboratory to experimental farms. One of the major advantages of experimental studies is the ability to document cause and effect, while observational studies identify associations. Associations between specific management strategies and agent prevalence do not prove cause and effect, regardless of the significance of their statistical tests.

Standardized Terminology

The study of farm management strategies is further complicated by the lack of standardized terminology and the variability instilled by individual producers. For instance, the term "quarantine and isolation" has long been touted as an effective means of preventing entry of specific diseases into a clean herd or flock. However, quarantine can be variously defined as segregating an animal in a separate stall or pen, maintaining a separate pasture or building, or providing a geographically isolated premise. Even the words premise, farm, and operation have no standard definition among animal scientists, veterinarians, economists, microbiologists, statisticians, and those in other disciplines involved in these studies.

A number of existing databases hold information relating to farm management strategies (table 2). Some examples of the information obtained from questions used to collect their data or outputs from these databases include herd size, building/feedlot design, feeding practices, contact with personnel, herd health histories, and pest control programs. Inventory estimates are most common in the national databases, while farm management characteristics are more common in farm record systems.

Farm Management Strategies for *E. coli* O157:H7 in Cattle

Studies of farm management strategies for *E. coli* O157:H7 are in their infancy. Hypothesized associations have grown out of the outbreak investigations, intensive followup of small groups of herds, and large-scale cross-sectional studies (USDA APHIS, 1994a). These studies have identified a number of statistical associations worthy of further study and include herd size, type of feeder, irrigation, feeding ionophores, grouping of calves prior to weaning, shared utensils, feeding oats, and feeding grain during the first week of life (table 3).

Many of the observed associations between *E. coli* O157:H7 and farm management strategies relate to feeding practices. The growth of *E. coli* O157:H7 in the digestive tract of cattle appears to be affected by feeding. Growth is inhibited in the experimental simulation of the rumen of well-fed cattle, but is unrestricted in

Table 2—Farm management and animal pathogen databases

Name	Purpose	Design	Reference population	Data types Farm mgt.	Data types Foodborne agents
Ag Census	National estimates	Census	Total U.S.	Some	No
NASS	National estimates	Probability sample	Total U.S.	No	No
FCRS (ERS)	National estimates	Probability sample	Total U.S.	Yes	No
NAHMS	National estimates	Probability sample	Total U.S.	Yes	Some
PigChamp	Farm records	Self-select	?	Yes	No
NVSL	Trends	Mandatory/vol. reports	Total U.S.	No	Some
VMDB	Case studies	Self-select	Veterinary colleges	No	Some
11 farm records	Farm records	Convenience	?	Yes	No
Diagnostic laboratories	Diagnoses/ business	Self-select	?	No	Some
Individual veterinarians	Diagnoses/ business	Self-select	?	Some	Some
PigMon	Farm records/ diagnosis	Self-select	?	Yes	No
Pork Quality Assurance	Quality	Self-select	?	Yes	No

Table 3—Association of _E. coli_ O157:H7 with selected management practices[1]

Management practice	Subgroup	Association with _E. coli_ O157:H7[2]
Small herd size[3,4]	Dairy farms	Pos., none
Use of computerized feeders[3]	Dairy farms	Pos.
Irrigation of pastures with manure slurry[3]	Dairy farms	Pos.
Feeding of whole cottonseed[3,5]	Dairy heifers and cows	Neg., neg.
Feeding of milk replacer[4,5]	Dairy calves	Neg., none
Feeding of ionophores[4,5]	Dairy calves	Pos., none
Grouping of calves prior to weaning[4,5]	Dairy calves	None, pos.
Sharing of unwashed feeding utensils among calves[5]	Dairy calves	Pos.
Feeding of oats in starter ration[5]	Dairy calves	Pos.
Feeding of grain during first week of life[4,5]	Dairy calves	None, pos.
Feeding of clover as first forage[5]	Dairy calves	Neg.

[1]Many other management factors have been tested for association with _E. coli_ O157:H7; only those listed were found to have statistical significance at $p \leq 0.10$.

[2]Pos. = positive association, i.e., management practice is associated with increased _E. coli_ O157:H7 prevalence. Neg. = negative association, i.e., management practice is associated with decreased _E. coli_ O157:H7 prevalence. None = no association.

[3]Hancock et al., 1994b.

[4]USDA APHIS, 1993.

[5]Garber et al., 1994.

rumen fluid from fasted cattle (Rasmussen et al., 1993). Therefore, feeding practices may influence colonization and shedding of _E. coli_ O157:H7 in cattle.

Cooperative efforts between USDA APHIS Veterinary Services, USDA ARS, Washington State University, the University of Wisconsin, and the University of Georgia have pushed forward a series of efforts to examine more closely management strategies potentially associated with _E. coli_ O157:H7, based on hypotheses generated by the USDA APHIS NAHMS studies and long-term field studies at Washington State University. One study is following herds over time to evaluate whether manure irrigation of pastures is associated with _E. coli_ O157:H7 prevalence (Hancock, 1994); another study followed farms with fecal-positive calves over time to elucidate shedding patterns (Gabber et al., 1994); and a third study is intensely monitoring a convenience sample of dairy farms to track the molecular epidemiology of _E. coli_ O157:H7 (Shere, 1994).

Farm Management Strategies for *Salmonella* in Swine

Factors involved in *Salmonella* in swine are complex and multifactorial. Control of the disease in swine, which may result in a more wholesome product for the consumer, may involve some combination of farm management, vaccination, improved processing, and consumer education (McCapes et al., 1991; Jay, 1992; Baird-Parker, 1990).

Investigations of affected farms have suggested that animals become infected from contaminated feed, from chronic carriers that are introduced into the population, from infected rodents, or from contact with infected farm personnel (Wilcock and Schwartz, 1992; Duhamel et al., 1992; Williams and Newell, 1968; Heard, 1969). Stress may play an important factor in reactivation of asymptomatic, nonshedding carrier pigs, which may contribute to increased environmental contamination levels (Morgan et al., 1987; Williams and Newell, 1970; Curtis and Backstrom, 1992).

At the abattoir, the initial source of contamination is the carrier pig. Transmission is thought to occur by pig-to-pig contact or from exposure to the contaminated physical environment (Newell and Williams, 1971). These infected animals are able to contaminate the area, equipment, and personnel which leads to contamination of the final product (Morgan et al., 1987; Newell and Williams, 1971; Williams and Newell, 1970).

Rodent Control

The role of mice in the epidemiology of salmonellosis is well documented on poultry farms (Henzler and Opitz, 1992), where it has been shown that house mice live in colonies on farmsteads. With access to food and water, mice generally do not travel far (Henzler and Opitz, 1992). Tablante and Lane (1989) were unable to recover *Salmonella* from barn environments and implicated mice as the source of infection in a dairy herd. In contrast, Henzler and Opitz (1992) were able to correlate an increase in the incidence of salmonellosis to infection of mice with *S. enteritidis*. However, poultry farms free of *S. enteritidis* still harbored other *Salmonella* in the environment (29.5 percent positive samples) and mice (6.0 percent positive samples) (Henzler and Opitz, 1992). Jones et al. (1991) observed a *Salmonella* contamination rate of 5.3 percent in mice in broiler systems. Mice are also potential vectors for transmission of *Salmonella* on swine farms (Duhamel et al., 1992). Other investigators have also suggested that rodents are likely vectors on swine farms (Wilcock and Schwartz, 1992; Schwartz, 1991).

Henzler and Opitz (1992) determined that mice infected with *S. enteritidis* can shed 2.3×10^5 CFU/fecal pellet and estimated the number of fecal pellets excreted in a 24-hour period to be approximately 100. Results from experimental studies conducted at USDA ARS NADC indicate that the minimum dose required to initiate infection in a pig is $\leq 10^4$ CFU for *S. typhimurium* (Fedorka-Cray and Stabel, 1993) and between 10^3 and 10^6 CFU for S. *choleraesuis* (Gray et al., 1994b). Other studies indicate that the levels required for infection may be significantly lower following natural exposure (Fedorka-Cray et al., 1994b; Gray et al., 1994c). Therefore, if the CFU/fecal pellet does not vary significantly between serotypes, it would be possible for a pig to become infected after exposure to only one fecal pellet. Joens (1980) demonstrated transmission of *Serpulina hyodysenteriae* by mice in a laboratory experiment and suggested that rodent populations in the field may act as constant reservoirs of infection, requiring a rodent eradication program to completely disinfect a facility.

The development of more effective control strategies for salmonellosis, focusing on changes in management and the environment that eliminate rodents from the premises, may be one step that is required before the elimination and prevention of salmonellosis on the farm or in swine facilities occur. A more detailed description of housing and environmental influences on production may be found elsewhere (Curtis and Backstrom, 1992).

Management Systems To Reduce/Eliminate Pathogens

Since it appears that initial contamination still occurs on the farm, emphasis should be placed on the farm level. In our experience, salmonellosis and its transmission is a problem that easily lends itself to simple controls that can be implemented on the farm. These include sanitation, modified rearing systems including isolation and limited access to facilities, and pest control programs. This does not mean that use of antibiotics and/or vaccination is not warranted. However, antibiotics are costly, and reports regarding the efficacy of antimicrobials have been mixed (Wilcock and Schwartz, 1991; Schwartz, 1991; Wilcock and Olander, 1978). This suggests that while the duration and magnitude of shedding may be altered, some level of environmental contamination will occur that may result in continuing or new infection, or reinfection. Therefore, the cycle of reinfection cannot be interrupted by antimicrobials alone. Vaccines have proved beneficial in reducing morbidity and mortality (Kramer, 1992).

In 1980, Alexander et al. (1980) developed a medicated early weaning (MEW) procedure in which *Mycoplasma hyopneumonia* was prevented from infecting naturally farrowed pigs. This program required that both sows and pigs be heavily medicated. Sows near term were removed from the source farm to a separate farrowing facility. Pigs were weaned at 5 days of age and placed in a separate nursery. From there, pigs were sent to another facility for grow-out. Based on these dramatic results, Harris (1988a, 1988b) proposed that economically significant diseases could be eliminated without depopulation by placing the various stages of production on multiple isolated locations. Harris (1990) modified the MEW procedure and found similar results if piglets were simply isolated from the source farm at weaning. Since 1988, both traditional pig farmers and integrated producers have modified old facilities or built new ones in either a three isolated site or a multiple isolated site design (Hammer, 1991; Fitzsimmons and Leman, 1991; Pillen, 1992; Harris, 1992; Harris et al., 1992). Multiple site production systems that utilize isolated weaning (Isowean^sm) have several advantages over traditional or classical methods of rearing pigs. These advantages are: (1) infectious agent elimination without the need of total depopulation; (2) enhanced performance of weaner through finisher pigs; (3) expansion of the breeding herd without depopulation; (4) commingling of young piglets from multiple sources with less risk of disease and/or improved performance and/or lower veterinary costs; and (5) improved efficiencies of labor/management (Harris, 1992). Alexander and Harris (1992) provide a more detailed discussion elsewhere.

Isolated weaning techniques have been utilized to produce pigs free of *Salmonella* for experimental purposes (Fedorka-Cray et al., 1994a) and to raise pigs free of *Salmonella* through to slaughter (Fedorka-Cray et al., 1994b). Regarding the raising of pigs for experimental purposes, pigs were weaned between 10 and 21 days of age and either transported to isolation facilities at NADC or farrowed at NADC and placed in isolation facilities. Pigs were raised in isolation, access was limited, and no medications were used. Approximately 366 pigs were free of *Salmonella* to 6 weeks of age. Control animals were maintained free of *Salmonella* through 24 weeks. These experiments demonstrated the feasibility of removing pigs from contaminated sows or environments and raising them free of *Salmonella* spp.

For the second experiment, one group of pigs remained on the source farm (the source farm was positive for *Salmonella* spp.), one group was transported to an offsite isolation facility, and one group was transported to isolation facilities at NADC. As we previously observed, we were able to demonstrate that use of isolated weaning resulted in pigs free of *Salmonella* spp. through

approximately 11 weeks (the control farm was positive at 11 weeks, while the other two facilities were negative at 11 weeks). However, at 11 weeks, the pigs at the source farm and the offsite isolation facility were moved to finisher units (pigs raised at NADC were kept in one isolation facility with limited access). At approximately 15 weeks, both the source farm pigs and the offsite group became positive for *Salmonella* spp. that were different than those originally isolated at the source farm. Contamination was most likely from environmental sources. All pigs at NADC remained free of *Salmonella* spp. through to slaughter. These data demonstrate the importance of sanitation and strict management control. They also indicate that it is possible to remove pigs from a contaminated environment and raise them free of *Salmonella* spp. to slaughter weight.

Implementation of HACCP

Until recently, HACCP plans for animal production had not been drafted. In June 1994, an HACCP workshop was conducted in Ames, Iowa, to establish a plan for use on swine farms. During this meeting, HACCP plans were constructed for five areas: (1) breeding, gestation, and farrowing; (2) nursery; (3) finishing; (4) artificial insemination center; and (5) feed. As a result of this meeting, studies are now being conducted to test the CCP's as outlined. Results from these studies should provide the criteria necessary for implementation of HACCP plans for all phases of swine production. The pathogen being monitored is *Salmonella*. These studies will also include some cost-benefit analysis that is currently unavailable.

Future Directions

There is no single database with a probability-based national sample of herds and both farm management and foodborne disease agent data. In fact, few existing databases hold information about both farm management strategies and agent prevalence. Furthermore, there are no national databases that pull together data obtained from outbreak investigations or experimental work.

Nevertheless, as demonstrated for *E. coli* O157:H7 in cattle and *Salmonella* in swine, numerous sources usually exist with some data on agent prevalence or farm management strategies. Ideally, existing data from different sources could be pulled together to create a dynamic database supporting economic analyses of the opportunities for cost-effective control strategies implemented at the farm level. Unfortunately, differences in definitions, reference populations, and database design produce incompatibilities. Therefore, the challenge remains to identify each of the numerous databases, characterize their unique strengths, and incorporate their

information to evaluate the role of farm management strategies for ensuring food safety at the production level. Regrettably, no systematic cross-reference or comparison of the terminology or designs used by these various databases has been prepared.

The HACCP approach has gained widespread support as the methodology of choice for addressing the entire food safety continuum, from farm to table (NLSMB, 1994). The HACCP approach is driven by data. However, pre-harvest data relating to the major foodborne disease agents of animal origin are scarce and disjointed. Government, industry, and academic study groups all have recommended additional resources targeted at preharvest food safety (NLSMB, 1994; USDA APHIS, 1994c; USDA APHIS, 1994d). Prevalence studies have become the highest priority for field studies to identify the relative frequency of specific pathogens on farms and their natural ecology. Correctly designed, the prevalence studies can provide a mechanism for generating hypotheses about the impact of specific farm management strategies. Outbreak investigations coupled with comparisons to farms not involved in the outbreak (controls) may also generate testable hypotheses. These hypotheses can further be evaluated through additional case control studies or cohort studies that follow farms practicing and not practicing the specific management strategy over time. Experimental work becomes critical at this stage to clarify whether the observed associations are causal in nature.

Conclusions and Recommendations

The *E. coli* O157:H7 and *Salmonella* foodborne disease outbreaks have changed public opinion and public policy. All of the affected parties, from the producer to the consumer, are demanding action to address the problem. The demands highlight and address: (1) the public expectation of an abundant, diverse, affordable, and safe food supply; (2) the producers', processors', and retailers' desire to expand markets for food and fiber; and (3) the taxpayers' calls to reduce taxes and trim Government expenditures. Despite widespread recognition of the challenges inherent in food safety policy, no tremendous outpouring of Government resources is predicted.

At the same time, production agriculture in the United States is changing, as documented by long-term trends toward fewer farmers and larger farms. The potential for foodborne disease outbreaks may increase as farms become larger and more contained and the demand for meat and meat-related products increases. The argument holds that the large farm size means that any emergence of a foodborne disease agent will affect a greater volume of animal products, therefore involving more consumers.

This line of reasoning is not a blanket condemnation of intensive management strategies, but rather a recognition of the size of individual production units at stake. At the same time, some intensive production practices allow greater control of agent, host, and environmental factors that determine animal health. From this aspect, intensive management strategies may lead to an overall safer food supply while capturing economies of scale to maintain low costs.

Additionally, all involved now agree that food safety is a shared responsibility, from the farmer to the consumer. No quick fix is projected. With the recognition of the complexity of the issue, discussions now focus on application of systemwide approaches such as HACCP. Application of HACCP principles for the prevention and control of foodborne agents such as *Salmonella* and *E. coli* O157:H7 will involve more attention to management strategies, including total quality control and support for continuous improvement throughout the food safety continuum. Recognition of the shared responsibility and the complexity of the issues reinforces the idea that no single institution—government, academic, or private—will single-handedly address all the needs. Food safety has become a rallying cry for renewed cooperation and collaboration. The issue requires multidisciplinary teams and multidimensional approaches. Data on pathogen prevalence and farm management strategies are a commodity to be shared in consideration of the scarce resources and the need for larger and more diverse work teams.

This conference was organized by NE–165, a committee with interests in agricultural economics. During the conceptualization and planning of the meeting, several of today's participants suggested that many in the audience simply wanted to know where the data are. The anticipated outcome of this session would be expanded accessibility to existing databases that could then be used to answer the most pressing issues surrounding the search for cost-effective strategies to improve food safety at the farm level. Our paper does not substantiate the existence of sufficient data to address all of the pressing problems faced in food safety. In fact, the naive observer might interpret today's presentation as a rather gloomy assessment of the limited data available and its incompatibilities.

Just as this presentation is a collaborative effort between a veterinary epidemiologist and a microbiologist, tracking foodborne pathogens from the farm to the table requires collaboration and breaking of old paradigms. The "ideal" database may never be developed, in part because the definition of "ideal" relative to food safety is evolving. New approaches to integrating observational and experimental research need to be developed. Rather than arguing the relative merits of observational or

experimental approaches or debating the contributions of animal scientists, food technologists, microbiologists, epidemiologists, and economists, all must focus on developing methods and tools for investigating

foodborne disease agents on the farm. We hope that this conference represents a major step in the development of these new and exciting approaches.

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Data Needed To Develop Microbial Food Safety Systems for Slaughter, Processing, and Distribution

Robert L. Buchanan
Food Safety and Inspection Service, U.S. Department of Agriculture

Gary R. Acuff
Texas A&M University

Brenda Halbrook
Food Safety and Inspection Service, U.S. Department of Agriculture

Current Food Safety Systems in Meat and Poultry Production

Foods of animal origin are derived from animals that live in close association with soil, water, air, and other environmental sources of micro-organisms, such as insects, rodents, and birds. Micro-organisms, including bacteria, are an expected and natural occurrence in the environment and will therefore establish themselves on the hide, hair, hooves, skin, feathers, and feet and in the gastrointestinal tract of live animals. Micro-organisms are acquired in the newly born or hatched animal through association with adult animals and the environment. Opportunities for cross-infection occur through contaminated vehicles and holding pens during transportation, especially because micro-organisms may be shed due to transportation stress. Micro-organisms associated with animals include human pathogens, although many are benign to their animal hosts, producing no symptoms of infection or disease.

Slaughter

There are few, if any, bacteria in the muscle tissue of normal, healthy live animals (Gill et al., 1978; Mackey and Derrick, 1979). After slaughter and processing, the bacteria contaminating a carcass are located primarily on the surface. The many sources of carcass contamination include contact with the external surface of the animal during hide removal, the gastrointestinal tract of the animal during evisceration (Nottingham, 1982), equipment and utensils used during processing (Mackey and Derrick, 1979), hands and garments of workers exposed to the carcass during processing, and air and water in the processing environment. The level of bacterial contamination of a carcass depends upon the degree of sanitation and hygiene practices during processing procedures, but numbers of bacteria ranging from 10^2 to 10^4 per cm^2 of carcass surface are not usually expected at this stage in processing (Nottingham, 1982; Johnston and Tompkin, 1992).

Types of Contamination

The microbial population on a carcass surface will most likely be made up of a variety of different bacteria originating from numerous sources. However, during refrigerated storage, only those bacteria capable of growth at refrigeration temperatures will become an increasingly significant and, ultimately, dominant part of the bacterial flora of the carcass surface. Most commonly, the resulting bacterial population is dominated by gram-negative, aerobic, psychrotrophic bacteria such as *Pseudomonas*, *Moraxella*, and *Acinetobacter* (Ingram and Dainty, 1971). Most of the bacteria making up the total population will have no public health significance in food, but some may be capable of causing illness in humans if consumed in sufficient numbers by a susceptible individual.

Pathogenic bacteria may be isolated at low levels from a varying percentage of raw meat and poultry products. These bacterial types include *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, *Clostridium perfringens*, *Escherichia coli* O157:H7, *Yersinia enterocolitica*, *Aeromonas hydrophila*, *Bacillus cereus*, and *Campylobacter jejuni*. Epidemiological data indicate that *Salmonella*, *C. perfringens* and *S. aureus* accounted for 94 percent of the outbreaks between 1973 and 1987 in which beef was implicated (Bean and Griffin, 1990). Likewise, these same three pathogens are most often accounted for in poultry outbreaks. Foodborne outbreaks attributed to *C. perfringens* and *S. aureus* are most commonly associated with improper handling and temperature abuse of foods of animal origin, typically in homes or food service establishments following cooking. Therefore, a hazard analysis would conclude that *Salmonella* and *E. coli* O157:H7 (due to recent outbreaks and sporadic cases) are currently the most important foodborne pathogens in which raw beef could be an important vehicle (USDA NACMCF, 1993). For raw poultry, *Salmonella* and *C. jejuni* (due to Centers for Disease Control and Prevention data indicating common sporadic occurrence of

poultry-associated campylobacteriosis) are considered the greatest microbiological hazards (Nachamkin et al., 1992).

Bacteria capable of causing foodborne disease can be expected to be found on a meat or poultry carcass surface; however, they vary greatly in number of cells present and carcasses contaminated and in location of possible contamination on the carcass. They cannot be entirely or reliably prevented from appearing through strict sanitary hygiene, nor can indicator organisms be used to reliably predict them (Tompkin, 1983). The U.S. Department of Agriculture's (USDA's) Nationwide Beef Microbiological Baseline Data Collection Program (USDA, 1994) for steers and heifers detected *Salmonella* and *E. coli* O157:H7 on only 4.0 percent and 0.2 percent, respectively, of more than 2,000 carcasses examined. In the 19 samples positive for *Salmonella*, the geometric mean number of organisms was 0.1, and the maximum level detected was 0.23 MPN/cm^2. In the four samples in which *E. coli* O157:H7 was detected, the maximum level observed was 0.93 MPN/cm^2. The presence of these pathogens is so variable that testing for their presence is extremely inefficient and unlikely to detect their presence except in random occurrences. Therefore, every carcass should be considered a potential source of low levels of pathogenic bacteria.

Current Control Methods

In practice, it is almost impossible to detect carcass contamination. In order to lessen the chance that carcasses might contain pathogenic bacteria, the most effective safety approach is to apply to every carcass preventive procedures designed to limit and reduce potential contamination. This is the driving force behind Hazard Analysis and Critical Control Point (HACCP) implementation. An HACCP system requires that hazards be identified by source and by possible critical control points (CCP's). Control is exerted at CCP's in the processing of raw meat and poultry through intensified hygienic practices designed to prevent contamination and through application of antimicrobial procedures designed to reduce the presence of pathogenic bacteria, whether they are present or not (Tompkin, 1990). These antimicrobial procedures may include sprays of dilute organic acids (lactic or acetic acid) or hot water, or treatment with trisodium phosphate (Powell and Cain, 1987; Smulders, 1987; Dickson and Anderson, 1992; Barkate et al., 1993; Siragusa and Dickson, 1993). This approach to food processing is designed so that every possible attempt is made to lessen the chance for contamination to every carcass.

Despite application of increasingly sophisticated processing procedures and of HACCP principles in the production of foods of animal origin, raw meat and poultry may still contain small numbers of bacteria capable of causing foodborne illness. Other than irradiation, there is no commercially applicable method to render raw meat and poultry free of pathogens. Insufficient cooking and improper handling are the overwhelming causes of food-borne illness associated with meat and poultry (Bean and Griffin, 1990). The prudent consumer therefore avoids consuming products that have been improperly handled and prepared.

Processing

After processing, the safety of meat and poultry products depends on its final composition, on organisms that survived processing, and on postprocessing contamination. Most processed products were developed through attempts to lengthen shelf life and improve quality, and a wide variety of products exists.

Perishable Raw Salted and Salted Cured Meats

This category of processed meat and poultry products includes items such as fresh pork sausage, fresh turkey sausage, Polish and Italian sausage, and uncooked ham and bacon. Retail packaging is provided in oxygen-permeable and oxygen-impermeable films. Cured products have been treated with solutions of nitrite and/or nitrate salts, sodium chloride, and cure accelerators, and many products have received mild heat and smoke treatments that dry exterior surfaces. Although processing is primarily designed to impart characteristic flavor to products and to lengthen shelf life, it is also expected somewhat to reduce micro-organisms of public health concern. However, it does not completely eliminate pathogens. Few bacterial foodborne diseases have been associated with perishable raw salted and salted cured meats, probably because consumers have traditionally cooked these products thoroughly before consuming them.

Shelf-Stable Raw Salted and Salted Cured Meats

Products in this category are coated with salt, sometimes including nitrite or nitrate, and stored at temperatures below 10° C. Recoating with salt occurs at regular intervals during the process. Final products, such as salt pork, dry cured bacon, and country cured ham, usually have a sufficiently high salt content to eliminate the need for refrigerated storage. Consumers in the United States normally cook these products before consumption; however, Europeans frequently consume them raw. Although some concern may exist about marketing these products at ambient temperatures, little evidence exists to suggest that they contain surviving micro-organisms of public health concern: these products have an excellent safety

record in the United States. A successful product depends upon control of temperature during salting/curing and proper penetration of the curing ingredients.

Cooked Uncured Meats

Products in this category are given a thorough heat treatment such that only spores and possibly some of the more thermoduric bacteria survive. Bacterial levels after cooking are determined by numbers and types present on the raw product before heating, the effectiveness of the thermal process, and the holding time-temperature profile after cooking. Recontamination of these products at low levels inevitably occurs from equipment and food handlers during postcooking handling, packaging, or serving. The USDA requires processors to provide a clear separation of cooked and raw meat and poultry products to prevent recontamination of cooked products with bacteria of raw-product origin. However, this separation is frequently violated by retail markets and consumers before consumption. Due to the probability of rapid growth of recontaminated pathogens in these products if stored at temperatures favorable for growth, USDA and most State regulatory agencies require that these products be stored at temperatures between 4° and 7° C. In most cases of foodborne disease associated with these products, critical flaws were detected in preparation or in holding and serving procedures at the food service or consumer level (Bryan, 1980).

Cooked Cured Meats

These products are cured with nitrite and salt and then given a heat treatment. This category includes products that are ready to eat (such as bologna and luncheon meat), that may be cooked before eating to improve flavor and texture (such as frankfurters), and that require cooking before consumption to ensure safety (such as some varieties of bacon). Opportunities exist for recontamination of exposed surfaces during chilling, holding, and packaging, and processors must ensure that processing-environment sanitation and handling practices are sufficient to control this hazard. Proper chilling and storage temperature following cooking and packaging are also essential for ensuring the safety of cooked cured meats. Likewise, prevention of cross-contamination and proper temperature control must be practiced at retail markets and food service facilities and in homes.

Fermented Sausages

Fermented sausages, such as pepperoni, summer sausage, and Genoa salami, undergo a lactic fermentation and depend upon production of organic acids, added salt, and drying for preservation. Some products may also be heated or smoked, which further reduces the presence of

bacteria in the final product. Control of growth and of enterotoxin production by *S. aureus* during fermentation is accomplished through proper process control to obtain rapid acid production. Additional potential problems include the possible survival and growth of salmonellae and, due to a recent outbreak in which dry fermented sausage was implicated, *E. coli* O157:H7.

Dried Meats

Commercial processing of dried meat usually involves a cooking step sufficient to eliminate vegetative bacteria, followed by a rapid drying procedure. Drying reduces the water activity of the product to levels inhibitory to pathogen growth. Home preparation of dried meat products with insufficient control of the process may allow growth of pathogens. Foodborne disease-causing bacteria are not usually present on commercially processed products; however, vegetative pathogens such as salmonellae that are not destroyed by heating or that are introduced to the product through recontamination may remain viable. Proper control of the process includes using meat of high microbiological quality, monitoring of time and temperature of drying, assurance of even drying, and drying to a sufficiently low moisture level.

Canned Meats

Products in this category include low-acid and acid-canned meats, shelf-stable canned cured meats, and perishable canned cured meats. Safety is assured through a balanced control of pH, water activity, salt, nitrite, heat processing, and container integrity, and, in the case of perishable products, refrigerated storage.

Distribution

Foodborne disease hazards in meat and poultry products, as affected by distribution practices, depend upon the category of product involved and the handling that the product receives. Fundamental problems include initial contamination levels on incoming products, contamination of the product during distribution, possible growth during improper holding procedures, and growth of pathogens to hazardous levels during extended storage at proper holding temperatures.

Products may be contaminated with pathogens during loading, transporting, and unloading. Sources include contaminated surfaces, hands of workers, insects, and contaminated air. However, the most common hazard associated with loading, transporting, and unloading is the potential for improper temperature control, allowing growth of existing pathogens to levels that may increase the probability of survival of the pathogen in a product ready for consumption. Assurance of safety in retail

systems requires good temperature control and handling appropriate to the product during distribution, warehouse storage, preparation for sale, and display. Refrigerated meats must be kept refrigerated; frozen meats must be kept frozen. Packaged and canned products must be protected from physical damage to the container. While a clear separation of raw and cooked products is regulated in plants that process products under USDA inspection, this separation often becomes obscure during distribution and presentation for retail sale. Cross-contamination of pathogenic bacteria from raw products to cooked, ready-to-eat products can easily occur during transportation, storage, preparation, and display for retail sale. Preparation and packaging of raw and cooked meat and poultry products often occur in close proximity, and retail display of raw and cooked products may not be separated at all. Handling of raw and cooked meat and poultry products may simultaneously occur at delicatessen counters. In addition, cross-contamination of cooked products or other foods not requiring heat processing can easily occur from customer handling of products during selection for purchase, checkout and bagging, and transport home.

Similar hazards exist in food service operations, but primary hazards include improper storage temperature, cross-contamination, and inadequate heat treatment of products before sale. The same hazards compromise the safety of meat and poultry products prepared for consumption in the home.

Current Data Collection

Current microbiological data collection in meat and poultry production ranges from little or none to extensive. Presented below is an example of microbiological sampling currently conducted by a commercial beef slaughter operation, based on information provided anonymously for this document.

Beef Slaughter Operation Microbiological Testing: An Example

Carcasses—Slaughter

Once per week on each shift, surface tissue samples are obtained from three carcass sides in three areas on each side (inside round, navel, and foreshank). Samples from the three sides are composited by area. Samples are examined for total plate count (TPC), lactic acid bacteria (LAB), coliforms, *E. coli* and fecal streptococci. A composite inside round, navel, and foreshank is examined for *Salmonella* and *Listeria*. A positive *Listeria* sample is confirmed for *L. monocytogenes*.

Carcasses—in Cooler, 24 Hours after Slaughter

Once per week on each shift, the same three carcass sides are sampled again in the same carcass areas (inside round, navel, and foreshank), and samples are again composited by area. Samples are examined for TPC, LAB, coliforms, *E. coli* and fecal streptococci. A composite inside round, navel, and foreshank is examined for *Salmonella* and *Listeria*. A positive *Listeria* sample is confirmed for *L. monocytogenes*.

Subprimal Cuts—Fabrication

Once per week, on the work day following slaughter samples, alternating shift samples are obtained from primal/subprimal pieces (chuck, clod, rib, skirt, top round, strip loin, top butt, and so on) from each cutting table. Three to eight pieces of each primal are sampled from interior cuts by taking a surface tissue sample from each until a composite of approximately 1 lb is produced. A trim sample is also collected (73's, 50's, or rough meats). Samples are examined for TPC, LAB, coliforms, *E. coli*, and *Staphylococcus aureus*. A composite sample is examined for *Salmonella* and *Listeria*, and a positive *Listeria* sample is confirmed for *L. monocytogenes*.

Ground Beef

Samples (1 lb) for various customers are taken from the blenders on a daily basis. Samples are also collected from the final product for evaluation. Samples are examined for TPC, LAB, coliforms, *E. coli*, *E. coli* O157:H7, and *S. aureus*. A composite sample is examined for *Salmonella* and *Listeria*, and a positive *Listeria* sample is confirmed for *L. monocytogenes*.

Sanitation—Preoperational

Kill floor and fabrication areas have a visual preoperational inspection performed by quality control prior to inspection by the USDA Food Safety and Inspection Service (FSIS). Once each week, preoperational swabs are obtained from contact and noncontact areas. Swab samples are examined for TPC and LAB, and a composite of the remaining buffer solution from swab samples is examined for *Listeria*.

Sanitation—Operational

Operational sanitation is visually monitored by production supervisors, through quality control, and by FSIS. On a random schedule, operational swabs are collected from slaughter, fabrication, and ground beef operations. Swab samples are examined for TPC and LAB, and a composite of the remaining buffer solution from swab samples is examined for *Listeria*.

Employee Hygiene

Employee hygiene is monitored daily. Fabrication employees' equipment is sanitized before use each day. Randomly selected employee equipment is swabbed every other week and examined for TPC and LAB.

This example of microbiological testing in a plant pertains to the issue of acquiring data for single plants. A limited number of larger studies have or are being conducted by FSIS to assess the overall status of the meat and poultry industry (USDA, 1994). These studies have been designed to obtain a statistically valid national estimate of the levels of a number of foodborne pathogens and to assess factors such as geographical and seasonal differences. Potentially, studies of this type could be used to assess the impact of various interventions on the frequency and levels of pathogenic species. However, the studies involve thousands of individual analyses; due to cost, they can be performed only on a very limited basis.

Acquisition and Protection of Proprietary Industry Data

Although extensive microbiological data may exist within the meat and poultry industry, most, if not all, are proprietary and unavailable for public analysis. Contribution of certain data to USDA for construction of a nationwide industry database could be of great benefit. Industry may see the Freedom of Information Act (FOIA) as a strong barrier to any sharing of data with government agencies for fear that their proprietary data would be made available to competitors. Exemption 4 of FOIA, however, protects "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential" (5 U.S.C. § 552(b)(4)). A trade secret is defined as a commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort (*Public Citizen Health Research Group* v. *FDA*, 704 F. 2d 1280, 1288 (D.C.Cir. 1983)). Commercial or financial information is defined as business sales statistics, research data, technical designs, customer and supplier lists, profit and loss data, overhead and operating costs, and information on financial condition (see, for example, *Landfair* v. *United States Department of the Army*, 645 F. Supp. 325, 327 (D.D.C. 1986)).

Exemption 4 can still apply to documents prepared by the Government that simply contain summaries or reformulations of information supplied by a source outside the Government. "To summarize, commercial or financial matter is 'confidential' for purposes of the exemption if disclosure of the information is likely to have either of the following effects: (1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained" (*National Parks & Conservation Association* v. *Morton*, 498 F. 2d 765, 770 (D.C.Cir. 1974)).

FOIA Exemption 4, then, allows proprietary research data to be exempt from disclosure. It is our hope that more companies will be inclined to contribute research data that will help establish databases to support the development of scientifically based regulatory and inspection programs.

Standardized Microbiological Procedures

The acquisition of microbiological data, particularly quantitative measurements, is highly dependent on the materials and methods employed. For example, the results of a simple "total aerobic plate count" would be expected to vary if one employed brain–heart infusion agar instead of tryptic–soy agar, incubated the plates for 48 hours instead of 24 hours, or held them at 25° C instead of 37° C. While there is some degree of methodological standardization (Vanderzant and Splittsoesser, 1992; AOAC, 1992), minor variations or incomplete reporting of conditions greatly restricts integration of data from different sources. In developing its soon-to-be-released book "Microorganisms in Foods, 5: Characteristics of Microbial Pathogens," the ICMSF found that a substantial portion of data in the literature lacked sufficient details on critical factors, such as pH, water activity, inoculum size, and heating and cooling rates, to allow full comparison between studies. The ICMSF is currently preparing recommendations on the key data that should be included in all food microbiology publications.

Data Needs for Process Evaluations and Risk Assessments

Data generation in the food industry is largely oriented toward assessing the status of a currently operating process. While these data may be of interest to the immediate user, serious thought must be given to the potential uses of the information before resources are committed that are needed to archive this information in integrated databases. Key questions that need to be asked during initial consideration of a new database include the following: Can the database help predict new situations? Can it be used to anticipate trends or problems before they reach critical levels? Can it allow for the identification of factors or interactions among variables that would not be possible experimentally? Are there practical ways of using the data once it is acquired?

One acknowledged need for the systematic collection of data related to the microbiological safety of foods is in the area of developing and performing risk assessments. Microbiological risk assessments require the evaluator to estimate three factors: the severity of the disease; the consumers' exposure to the microbial agent; and the relationship between the extent of the exposure and the incidence of disease in a population. A great deal of attention has been focused on estimating the last factor through establishment of dose-response relationships. For example, a rationale for epidemiological databases is to acquire these quantitative relationships. Once the severity and dose-response relationship for a foodborne disease has been established, the key factor is the population's level of exposure. Unless one is postulating a change in the population with regard to its susceptibility to the disease agent, the dose-response relationship should remain reasonably constant.

Unlike chemical risk assessments, where the levels of a toxic compound are likely to remain steady or slowly decline over time, microbial populations can change rapidly. If placed in an environment that supports its growth, pathogenic bacteria can increase a billionfold overnight. Conversely, large populations can be eliminated in an instant if exposed to conditions that inactivate the micro-organism. Bacterial levels may remain unchanged for extended periods if the environment allows the microbial population to remain dormant. Considering the complexity of most foods and of the production, processing, distribution, marketing, and preparation chains associated with their use, it is not surprising that it has been difficult to anticipate the consumer's level of exposure without specifically analyzing the piece of food that they are about to consume.

During the past several years, an international group of scientists has tried to overcome this limitation through development and application of techniques in predictive microbiology (McMeekin et al., 1992; Whiting and Buchanan, 1994). Put simply, they have used mathematical expressions to describe how a micro-organism responds to its environment. Assuming that micro-organisms respond predictably, then if the key factors that influence a micro-organism's growth and survival are understood, its behavior in new situations can be predicted. What is not generally appreciated, however, is that these mathematical descriptors are only as good as the data from which they are derived. Typically, three and four variable models have been developed using data sets where the behavior of a micro-organism under as many as several hundred unique combinations of the independent variables has been systematically assessed and recorded (Gibson et al., 1988; Buchanan and Phillips, 1990; Buchanan and Klawitter, 1992; Zaika et al., 1992; Buchanan et al., 1993 and 1994). The more data

available, the greater the range and accuracy of the model. Although the different modeling approaches may offer certain advantages, researchers generally concede that the true key to the development of predictive models is having access to good data sets. Several research groups have large experimental databases that have been collected systematically over the past decade.

The need for large data sets is also critical when validating predictive models. This involves comparing the microbial behavior predicted by a model against observed data in as wide a variety of foods as possible. The availability of a database that consolidates experimentally observed data on foodborne pathogens in a variety of foods would be of great benefit to researchers, industry, and regulatory bodies. Such a database has been established for internal use by the Institute of Food Research, part of the United Kingdom's Ministry of Agriculture, Fisheries, and Food (MAFF).

A way of immediately enhancing the development of these large databases would be to combine the existing databases. A hurdle to overcome, however, is the controversy concerning the protection of intellectual property rights. Data sets of the type being discussed are very expensive to generate. For example, it is estimated that USDA and MAFF projects in predictive modeling together have invested between $25 and $30 million in acquiring the data needed to develop useful microbial food safety models. The United States, United Kingdom, and other countries are currently discussing means by which they can pool their resources while still safeguarding their investment.

Although the current program in predictive microbiology is a good start on acquiring the systematic data that will be needed to perform realistic microbial risk assessments, it is only the first step in what can be an increasingly sophisticated means of making decisions about food processes and practices based on scientifically acquired data. Ideally, one would be able to use computer simulation processes similar to those used in weather forecasting to explore how changes in food processing and preparation practices are likely to influence a product's microbiological safety.

Buchanan and Whiting (1995) have suggested that predictive microbiological modeling could be realized by breaking the complex chain of events associated with the manufacture, preparation, and consumption of foods into discrete steps. Models for each of the steps could be developed and "strung together" to provide an estimate of the combined effect of any number of different steps. The concept focuses on the development of computer simulations; the authors identified three types of data that would be needed: the frequency and levels of foodborne

pathogens in raw ingredients; the growth and survival characteristics of foodborne pathogens as a function of various environmental parameters (such as temperature, pH, and water activity); and the effect of individual food processing and preparation steps on these environmental parameters. Such a process has been used quite successfully in the development of sophisticated computer simulations of food quality attributes. The USDA, for example, has developed a highly effective simulator for predicting yield and quality attributes for the processing of potatoes (Kozempel et al., 1995).

It is obvious that to use this approach to develop generalized simulations related to food safety will require data beyond the capabilities of any single organization. Some of the data are already being acquired. USDA baseline studies are providing estimates of the frequency and extent of foodborne pathogens in various raw meat and poultry products. As technology changes, however, so will these values. A long-term effort is needed to periodically update these data. The databases generated by the predictive microbiologists have made a good start in acquiring data on the effects of the behavior of foodborne pathogens in response to some of the key factors influencing their growth and survival. But these data are just beginning to be generated. For databases to be fully effective, additional variables will have to be considered and verified. Finally, systematic experimental data are needed on the characteristics of various foods and how they are influenced by various processing and preparation steps. It should be possible to acquire much of these data from industry or their respective trade organizations.

If industry data are to be made available—a potentially powerful tool—there must be cooperative development of centralized data resources. Interest has been expressed in establishing a clearinghouse for that purpose. Synthesizing data, however, will require standardized data acquisition and reporting. Furthermore, the issue of safeguarding intellectual property rights and protecting proprietary information must be resolved.

Data Needs for HACCP Programs

Increasingly, HACCP is being applied to food processing. Recordkeeping is an integral component of HACCP, and some of these data could be useful additions to a national database. But data should not be collected for their own sake, and information generated for discrete plants may not be useful to a wider audience. The four criteria previously mentioned should serve as guideposts in assessing the broader usefulness of data collected for a particular plant. The potential volume of data makes their careful management important.

There may be information and data needs that extend beyond the slaughterhouse door to the consumer, or back to the farm and point of origin. It has been suggested (Hathaway and McKenzie, 1991), for example, that an animal's age, species, and pertinent environmental conditions, such as the season of the year and geographic region, be noted when using an HAACP plan, because it could affect the animal's condition. The origin and health status of herds and flocks could be determined in advance so that high-risk animals could be stratified and separated from low-risk animals for both slaughter and inspection. These data, in combination with pathogen baseline data and microbiological profiles of products, could help identify farm management and animal marketing practices that affect food safety.

Data Needs During Processing and Distribution

A HACCP analysis of processing steps will help identify and dictate the activities and interventions with the greatest impact on improving the microbial profile of the final product.

There is some controversy regarding the role that volume of processing plays in the contamination of carcasses. High-volume beef slaughter establishments have been found (Hogue et al., 1993) to be more effective in reducing total aerobic counts on briskets and ground beef than low-volume establishments. Reductions in counts may have been due to better methods of reducing carcass contamination during slaughter and better methods of contamination removal. Some improvement was also due to the uniform size and weight of the cattle being slaughtered and to more efficient chilling of carcasses in the first 18 to 24 hours after slaughter. Data such as these are relevant to a broad spectrum of processors and research scientists. These data indicate the processing steps and interventions that have the greatest and most predictable effect on the microbial quality of the final product. Gathering data such as these and synthesizing them with other data collected at a number of establishments would indicate whether there is a trend toward a better microbial profile of the final product when specific interventions or processing steps are applied. Such analyses would provide a basis for reasonable expectations related to the effectiveness of process controls, identifying factors that influence intervention efficiency, and optimizing process performance.

Industry could be of great assistance by supplying data collected in their quality control programs.

Data Collection

One of the best means of collecting continuous feedback data is to use sensors and automated data acquisition systems. A variety of advances in technology have been applied to industries, such as wood chip pulping for paper manufacture and the production of lubrication oils distilled from petroleum, and they have yielded great progress in process control (Caro, 1991). Some of these same techniques are being applied to the food industry. The physical properties and composition of the raw materials are measured and tightly controlled so that the final product is highly predictable. Sensors are used to measure parameters such as pH, viscosity, weight, temperature, color, flow rate, conductivity, moisture, density, and pressure. A variety of sensors, such as ultrasonics, vision systems, near-infrared, and electro-optics, are increasingly sophisticated and may be useful in food process control (Selman, 1989). The slaughter and processing environment is harsh due to high or low temperatures, moisture in the plant, and dust, which necessitate a control system and sensors that are rugged enough for the plant floor (Richardson, 1989). Data collected through sensors can be used for process control.

User-Oriented System Critical

Ultimately, the desirability of systematically collecting and compiling information into database systems depends on whether it will be useful to, and used by, the food industry and associated regulatory agencies to enhance food safety. The complex nature of food safety, due to the many variables and interactions that can affect hazard control from the farm to the consumer, demands an integrated approach. However, lack of communication among the scientific disciplines involved at various points in the continuum from farm to table greatly hampers the exchange of ideas. This, in turn, significantly lessens the potential for achieving the required broad viewpoint. The development of integrated databases may offer a way of overcoming this obstacle. However, the same barriers that stop effective communication could potentially limit the effectiveness of food safety data systems.

Key to developing a useful tool is bringing the various segments together to learn each other's "language" and approaches. Likewise, substantial effort must be made in designing a system that is sufficiently user-friendly to all, taking into account each potential user's needs and capabilities. Without this effort, a potentially important tool will languish as an expensive, little-used archive, of limited use as a research tool and with little impact on developing new solutions to food safety problems. Under these circumstances, it is doubtful whether the commitment of public and private resources that would be required to produce the database would be justified. As in golf, what needs to be done is clear, but success is measured in the followthrough. Discussing these matters is an important first step in developing the required understanding of our capabilities, approaches, and mutual needs.

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Tracking Foodborne Pathogen Data from Farm to Retail: Comments

George Beran
Iowa State University

The coming together of an emphasis on the pathogenic microbiology of meat from normal animals is new, as is a focus on the origin of microbial hazards throughout the food chain from production through transport, slaughter, fabrication, processing, distribution, warehousing, retailing, and final preparation at food service establishments and in homes. The impetus for this stems largely from recent widespread epidemics of meatborne *Escherichia coli* O157:H7 and of salmonellosis contracted from dairy products—epidemics that occurred just as the Hazard Analysis Critical Control Point (HACCP) system of hazard prevention had begun to be seriously examined. Table 1 shows the relationship between meatborne pathogens and the severity of related human diseases.

Citing these two developments, the session focused on microbial hazards in meat and meat products from apparently healthy animals and in poultry and poultry products from apparently healthy birds that were butchered, processed, and handled as would normally be expected. The paucity of microbiological data that can be correlated from production to consumption is astounding; where partial data collections have been made by industry, they are largely proprietary and mostly applicable to specific situations. Table 2 shows the critical sources of 26 foodborne pathogens and their impacts on human health.

The session focused on the need for microbiological data on live animals, from production to the abattoirs, as carriers of human pathogens. Baseline data, management approaches to pathogen control, and cost/benefits of pathogen control at production level are critical needs. One significant production study in swine is demonstrating that age-segregated rearing is effective in reducing or eliminating *Salmonella*. From slaughter of food animals to final consumption, data are needed on the hazards of pathogens that are brought into the abattoirs in or on the slaughter animals, pathogens that cross-contaminate animal products, and pathogens that are acquired by environmental contamination. Again, baseline data, process controls for pathogen reduction/elimination, and cost/benefits of approaches to prevent or remove contaminants are critically needed. Only passing attention was paid to human contamination of products from production to consumption; yet this, too, is a critical area of data deficit.

Some valuable guidelines were developed in the session for collecting, validating, and utilizing the greatly needed data. Techniques in predictive microbiology were projected as highly applicable. Along with hazard assessments and action at critical control points, there must be cost/benefit studies.

Table 1—Prevalence of meatborne pathogens and severity of human disease

Human pathogens	Prevalence on meat score				Human disease severity score
	Pork	Beef	Lamb	Poultry	
Salmonella spp.	1.5	1.8	3.1	2.2	3.0
Campylobacter spp.	1.0	1.2	1.8	3.0	2.5
Yersinia spp.	1.8	0.2	–	–	1.5
Aeromonas spp.	3.0	1.8	3.3	3.2	1.0
Arcobacter spp.	3.8	–	–	–	1.0
Erysipelothrix spp.	2.0	–	–	–	2.0
Leptospira spp.	2.0	2.0	0.5	–	2.0
M. avium	2.0	–	–	1.0	1.5
M. bovis	–	0.1	–	–	4.0
B. abortus	–	0.3	–	–	4.0
B. suis	1.0	–	–	–	4.0
E. coli O157:H7	0.2	1.5	0.2	0.2	3.0
Coxiella burnetti	–	1.0	2.0	–	2.5
Cryptosporidium spp.	–	2.0	1.0	–	2.0
Toxoplasma spp.	2.0	1.2	1.5	1.0	2.5
Trichinella spp.	1.0	–	–	–	3.0
C. cellulosae	1.0	–	–	–	2.0
C. bovis	–	1.0	–	–	1.0
Listeria spp.	1.8	1.8	2.2	2.0	2.0
C. perfringens	2.8	1.8	3.6	3.6	1.5
C. botulinum	0.2	–	–	–	4.0
B. cereus	1.1	1.3	–	2.0	1.5
Staphylococcus spp.	3.0	3.4	–	2.5	2.0
Shigella spp.	0.2	0.2	0.2	0.1	3.0
Hepatitis A virus	0.2	0.2	0.2	0.1	4.0
Norwalk virus	0.3	0.3	0.3	0.2	2.5

– = Insufficient reports available.

Note: Mean percentages of contamination of meats and products by the reported organisms were converted to the scores on the following basis: 0–9 percent = 0–1.0 (rare); 10–29 percent = 1.1–2.0 (low); 30–40 percent = 2.1–3.0 (moderate); and 50–100 percent = 3.1–4.0 (high), with proportional increments between.

The severity of human disease in infections and intoxications by foodborne pathogens was qualitatively assigned on the basis of published survey reports or expert consensus for infections and intoxications. The following severity scores were qualitatively defined: 0–1.0 (negligible); 1.1–2.0 (low); 2.1–3.0 (moderate); 3.1–4.0 (high).

Source: George Beran (Chair), Technical Analysis Group Report on Slaughter to the Food Safety and Inspection Service, U.S. Department of Agriculture.

Table 2—Health impacts of 26 foodborne pathogens

Human pathogens	Critical source	Swine Impact	Swine Rank	Cattle Impact	Cattle Rank	Lamb Impact	Lamb Rank	Poultry Impact	Poultry Rank
Salmonella spp.	Animals	4.5	3	5.4	2	9.5	1	6.6	2
Campylobacter spp.	Animals	2.5	10	3.0	4	4.5	4	7.5	1
Yersinia spp.	Animals	2.7	9	0.3	14	–	–	–	–
Aeromonas spp.	Animals	3.0	8	1.8	8	3.3	7	–	–
Arcobacter spp.	Animals	3.8	6	–	–	–	–	–	–
Erysipelothrix spp.	Animals	4.0	5	–	–	–	–	–	–
Leptospira spp.	Animals	4.0	5	4.0	3	1.0	9	–	–
M. avium	Animals	3.0	8	–	–	–	–	1.5	–
M. bovis	Animals	–	–	0.6	13	–	–	–	–
B. abortus	Animals	–	–	1.2	10	–	–	–	–
B. suis	Animals	4.0	5	–	–	–	–	–	–
E. coli O157:H7	Animals/Humans	0.6	14	1.5	9	0.6	11	0.6	10
Coxiella burnetti	Animals	–	–	2.5	6	5.0	3	–	–
Cryptosporidium spp.	Animals	–	–	4.0	3	2.0	8	–	–
Toxoplasma spp.	Animals	5.0	2	3.0	4	3.8	6	2.5	–
Trichinella spp.	Animals	3.0	8	–	–	–	–	–	–
C. cellulosae	Animals	2.0	11	–	–	–	–	–	–
C. bovis	Animals	–	–	1.0	11	–	–	–	–
Listeria spp.	Environment	3.6	7	4.0	3	4.4	5	4.0	5
C. perfringens	Environment	4.2	4	2.7	5	5.4	2	5.4	3
C. botulinum	Environment	0.8	13	–	–	–	–	–	–
B. cereus	Environment	1.6	12	2.0	17	–	–	3.0	–
Staphylococcus spp.	Humans	6.0	1	6.8	1	–	–	5.0	4
Shigella spp.	Humans	0.6	14	0.6	13	0.6	11	0.5	13
Hepatitis A virus	Humans	0.8	13	0.8	12	0.8	10	0.4	12
Norwalk virus	Humans	0.8	13	0.8	12	0.8	10	0.5	11

– = Insufficient reports available.

Note: Impact scores 0–12.0 are classed as negligible, 12.1–24.0 as low, 24.1–36.0 as moderate, and 36.1 or above as high. Impact figures are based on published reports or, where published reports do not support quantitative assessment, on expert estimates of prevalence. These health impacts are calculated by multiplying the mean prevalence on meat and meat products score by the transmissibility by meat score by the severity of human infections score.

Source: George Beran (Chair), Technical Analysis Group Report on Slaughter to the Food Safety and Inspection Service, U.S. Department of Agriculture.

Tracking Foodborne Pathogen Data from Farm to Retail: Comments

Irene V. Wesley

National Animal Disease Center, USDA Agricultural Research Service

Livestock are a major source of foodborne pathogens that are targeted for reduction in the Centers for Disease Control and Prevention document "Healthy People 2000." Baseline 1987 data (human cases per 100,000 population) and the goals to be achieved for each pathogen by the year 2000 are summarized below (National Center for Health Statistics, 1994). Since livestock are potential carriers of human pathogens, minimizing the on-farm prevalence of these agents will have an impact on reducing human cases of foodborne illness by the year 2000.

Cases (per 100,000)	1987	2000
Campylobacter jejuni	50	25
Salmonella spp.	18	16
Escherichia coli O157:H7	8	4
Listeria monocytogenes	0.7	0.5

A comparable document, hypothetically entitled "Healthy Livestock 2000," which sets goals for reducing the prevalence of these foodborne pathogens in livestock, is yet to be drafted. However, a team from the USDA Animal and Plant Health Inspection Service's (APHIS's) National Animal Health Monitoring Survey (NAHMS) is implementing studies to gauge the prevalence in the Nation's herds of these bacteria that are significant to human public health. Such data are a prerequisite to setting reduction goals and to defining intervention strategies in order to reduce the national on-farm prevalence of zoonotic foodborne pathogens. The 1995 NAHMS swine survey (Swine '95) "will provide a general overview of management and animal health on all sizes and phases of swine operations." The survey will also incorporate data on the prevalence of foodborne pathogens such as *Salmonella* spp. and *E. coli* O157:H7, based on fecal culture of samples collected on the farm. The public health importance of *E. coli* O157:H7 and the susceptibility of neonatal pigs to experimental infection (Francis et al., 1989) justified its inclusion in this national swine census. The NAHMS dairy survey slated for 1996 is in the early planning stages and will undoubtedly include some of the "big four" microbes highlighted in the "Healthy People 2000" mandate. Although yet to be finalized, the NAHMS poultry study may focus on

C. jejuni. The Food Safety Inspection Service (FSIS) postharvest microbial baseline studies complement the on-farm preharvest efforts of APHIS. For example, the FSIS study of hog carcasses scheduled in 1995 will provide baseline data on *Salmonella* spp. that can be compared with the NAHMS on-farm Swine '95 results. Thus, the NAHMS data will track the national and regional prevalence of the four major zoonotic foodborne pathogens and will provide a yardstick by which the success of pathogen reduction programs in the national herd can be measured.

The papers presented during this session probe the futuristic approaches to foodborne pathogen control. Although antibiotics and vaccine regimens are currently in vogue, alternative tactics for lowering the prevalence of foodborne pathogens have been explored. Segregated early weaning, which was originally proposed to improve animal production and to reduce the prevalence of swine pathogens, is being evaluated as an on-farm intervention strategy to reduce zoonotic food-borne pathogens. It is conceivable that swine commensals, such as *Campylobacter coli,* will respond differently than frank swine pathogens to such management strategies. Methods to boost the general immune competence of livestock to minimize their pathogen load, and thus circumvent the use of antibiotics and the withdrawal period required for their use, have been proposed at the National Animal Disease Center.

Feed withdrawal may seem a logical intervention strategy for reducing fecal carcass contamination. However, studies by Rasmussen et al. (1993) suggest that such practices done prior to slaughter may favor the multiplication of *E. coli* O157:H7. In analogous studies, Holt et al. (1993, 1994) have shown that feed withdrawal, while inducing molt in poultry, increased the shedding of *Salmonella enteritidis.* It is unknown whether feed withdrawal impacts the replication of foodborne pathogens in swine. We have demonstrated that dexamethasone, which simulates the stress associated with transporting, crowding, and weather extremes, increased the shedding of *L. monocytogenes* in the milk of chronically infected dairy cows (Wesley et al., 1989).

Recently, APHIS mobilized four focus groups to address and to prioritize areas of research for:

- *E. coli* O157:H7

- *S. enteritis* and *Campylobacter* in poultry

- Other *Salmonella* in cattle and swine

- Parasites of swine

Focus group summaries frequently noted the need for studies to determine the *prevalence rate* and the *economic impact* of these pathogens. To estimate the prevalence rates requires rapid and sensitive screening methods. Molecular techniques for tracing the spread of each of the four major foodborne pathogens are available. A multiplex polymerase chain reaction (PCR) that differentiates *L. monocytogenes* from other *Listeria* has been developed. A PCR-based system that may, in the near future, rapidly screen for *C. jejuni* shows promise of detecting this fastidious microbe in livestock feces in less than 8 hours. A futuristic goal is to design of a multiplex PCR system with primers to simultaneously screen for each of the four major foodborne pathogens in one reaction tube. However, as we develop increasingly more sensitive diagnostic tests, two dilemmas arise: What do

we do with the data, and how do we handle the livestock carrier, especially as we deal with commensal organisms that become pathogenic in humans? To paraphrase one of our speakers, "How can we subsequently *manage* what we have *measured*?"

The "Healthy People 2000" document has served to rivet our attention on the major bacteria of public health significance. We, as microbiologists, veterinarians, and clinicians, however, should maintain our vigilance on the emergence of as yet undescribed zoonotic foodborne pathogens. It is significant that *Campylobacter* spp. were reported in livestock abortions before they were recognized as significant human foodborne pathogens. Likewise, *Arcobacter butlzeri*, which is a campylobacter-like organism, was cultured from aborted livestock fetuses prior to its recognition as a cause of human enteritis (see the review by Wesley, 1994). Undoubtedly, other foodborne agents will be detected in livestock before they become human public health concerns. In conclusion, this workshop clearly underscores the advantages of a multidimensional approach in achieving a "Healthy Livestock 2000."

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Tracking Foodborne Pathogen Data from Farm to Retail: Comments

Dane Bernard
National Food Processors' Association

First, I would like to extend my compliments to the presenters for two very fine papers. For purposes of discussion, I would like to review a few points. Both papers have supported many common themes, including the opinion that enhancing the safety of our food will take a cooperative effort that views the food supply as a continuum, with each segment in that continuum having a role to play. This must include proper handling and preparation, as well as needed controls in all segments in the chain leading up to the consumer. This is a point with which the National Food Processors' Association (NFPA) absolutely agrees.

In addition, it was stated that tracking foodborne pathogens from farm to table requires collaboration and breaking of old paradigms, and that no quick fix is projected. I would also assert that this is true not only about tracking pathogens, but also in regard to reducing their incidence in raw animal products. There are many reasons for this, including a lack of ecological information regarding where pathogens exist in nature and how they are transmitted. I would also add that fundamental changes in the way that our food supply is inspected would enhance the potential for continued improvement in the microbiological character of meat and poultry products. Because there are so many pieces to the puzzle, we must view this as an evolutionary process that will be hastened only by collaboration and cooperation among all segments of the food chain.

Both papers have also mentioned the use of Hazard Analysis Critical Control Points (HACCP) as a safety management tool that depends on the scientific data to conduct a comprehensive hazard analysis. While we believe that HACCP can be applied to all segments of the food chain, including production agriculture, we must be careful not to oversell its potential. HACCP has already become a buzzword in food safety circles, but it must be clear that it is not magic and that no management scheme will cure all potential food safety problems. An HACCP plan is only as good as the data available during its development. HACCP cannot prevent problems when we have insufficient knowledge about the ecology of pathogens. Only with such knowledge can we establish effective control points. I fully support the position of Hueston and Fedorka-Cray in their encouragement of studies that will help determine where pathogens occur in nature and what intervention strategies may be used in the production sector to reduce their incidence in animals for slaughter. It is worth considering, though, how we would implement such strategies across an agricultural sector that is very diverse, is not always technically sophisticated, and presents only limited opportunities for control of pathogens.

In reviewing the comprehensive paper by Buchanan, Acuff, and Halbrook, there are two significant points I would like to address. The concept of predictive modeling as a tool to assess the safety of food products is an approach that the NFPA enthusiastically endorses. But, as noted in the paper, validation of models will be vital to their future use. In addition, the data that have been generated by Government-funded studies (referred to by the authors) should be made generally accessible so that the food industry can develop greater confidence in the models developed from the data. If data are not shared, the industry will be reluctant to embrace the models. Sharing the information beyond Government bodies will help to demystify the concept and promote wider acceptance.

Buchanan, Acuff, and Halbrook also discuss the problems of collecting microbiological data with which to evaluate the effectiveness of various process interventions. They note that extensive microbiological data may exist within the industry, but are mostly proprietary and not available for public analysis. To have access to these data would undoubtedly be of great interest to the food safety community; however, convincing the industry to share this information will not be easy. For various reasons, the industry does not feel comfortable with sharing such information. As a possible solution, a clearinghouse approach to sharing such data should be considered. Making a third party responsible for summarizing the data on a generic basis may be one way of gathering such information.

Tracking Foodborne Pathogen Data from Farm to Retail: Comments

James B. Kliebenstein
Iowa State University

Introduction

This conference had a very good start this morning when Julie Caswell pointed out that the policy options for food safety need to be evaluated with the best science and the best social science involved. This challenge needs to be kept in the forefront in the food safety arena.

The organizers of this conference are to be commended for the excellent program that they have put together. The conference has been an excellent forum to get us to focus on what is needed first and foremost in the food safety arena. All of us are challenged to, first of all, think about where we need to go and what is needed as we address the issues. Moreover, we are encouraged to first take a step back to view what we know, how things appear, and what is presently available. By doing this, we can better identify what we need to add to our current body of knowledge.

It is clear that food safety issues cover the entire food industry continuum, not just a particular sector. The paper by Hueston and Fedorka-Cray focuses strongly on the preharvest area of food safety. The paper by Buchanan, Acuff, and Halbrook focuses more on postharvest food safety issues. Both papers are excellent and force us to think about some of the primary issues in their respective areas. However, one area that has been overlooked in this continuum is that of the input supplier. The food safety chain begins with the input supplier and continues through to the table of the consumer.

Another common ingredient flowing through this conference is the need for cooperative efforts throughout the industry. Hazard Analysis/Critical Control Point (HACCP) studies need to recognize this as well. Many HACCP studies have focused only on a small segment of the food chain continuum. This focus must be expanded as we move to develop a broader perspective of the entire food safety continuum. To do so requires an integrated data system that will allow cost-effective analysis of the meat and meat product food chain or system. That is the overriding theme of this entire conference, and we must not lose sight of it.

Special or singular interests must be compromised in the interest of societal concerns (benefits) in order for us to have effective multidisciplinary research or interaction of multidisciplinary interest groups on many of the food safety issues. No one group will get all its wishes. At this particular conference, it appears as though some singular interests have surfaced. Proceeding with a singular interest in a multidisciplinary area will only slow progress in that area.

Data System Development and Use

With the continuing demand to use resources more effectively, we cannot expect the current level of resources to remain unchanged. The issue of developing an integrated data system is quite simply that of economics. It is not really about whether one should be developed, but more *when* and *how* it will be developed. Such a system, if done properly, can be very cost-effective and eliminate the need for the large number of independent data sources that we currently have for particular sections of the food chain. Rather than waiting until there is no alternative, why not start now? To set up this integrated data set, first we must identify what we already know or what data are currently available. We must look at the strengths of the data that we have, and then determine what else we need to address the issues and problems within the food safety arena.

As pointed out quite clearly in this session, data collection in the past has much too often been focused on the initial user. Little thought has been given to multiple users of such a data set. Moreover, there have been no coordinated efforts for data collection. When collecting data of this type, it is common that the marginal benefits we gain from asking more questions far outweigh the marginal costs of obtaining the data. In many cases, the farm, the plant, or other data collection areas have already been visited. Many of the upfront costs have already been borne, so it is just a matter of a little more time to collect additional information that may be quite useful.

Another common theme running through the two sessions has been the need for a food supply that is as safe as technically possible. This theme should be expanded to include the economic feasibility of providing such technically safe food. Studies have shown that consumers have a limited willingness to pay for enhanced food safety.

Therefore, the bottom line is that consumers are not necessarily willing to pay the price to get the probability of foodborne illness down to zero. Similarly, it should be recognized that critical control points for key pathogen entry into the food system need to be evaluated, both with respect to the amount and cost-effectiveness of that pathogen reduction.

Communication and common language were emphasized, especially in the paper by Hueston and Fedorka-Cray, as yet another key in food safety issues, or, for that matter, in any type of analysis. They are absolutely essential in order to establish an integrated database. It has been pointed out that, with the level of information that we are able to obtain and store using computers, we are rapidly entering what may be termed the communication era. This is especially true for multidisciplinary efforts. We need a standardized terminology or language that clearly communicates to a variety of audiences. We must establish a common language for food safety in order to avoid problems that will arise when we create the integrated database.

Cost-effective HACCP or food safety strategies imply cost-effective research and data collection. Cost-effective research ensures that we clearly identify the problem, then look at the issue in terms of what we do and do not know. The idea of a clearinghouse for data standardization, collection, and distribution in the food safety arena was brought up in the paper by Buchanan, Acuff, and Halbrook. It has been suggested that it might be called the Center for Epidemiologic and Health Information. I am sure that other names will be suggested, but the bottom line is that we do need to establish a center of this type. Deciding what type of data will be collected, standardizing the data, locating the central collection point, and other decisions associated with a center of this type must be made.

The need for scientific information about food safety and the quality of food products has been discussed at much length at this conference. We must remember that perception is reality when consumers make decisions about food purchases. Scientific information impacts food purchases if it matches perception. By itself, it has little impact on these decisions. Therefore, effective communication at all levels of society about food safety and processes in the food channel is extremely important. If perception is out of line with scientific information, we need to concentrate on consumer education. This returns to the communication issue discussed previously. It is vitally important that communication that hinges on scientific information is effective. Information is effective only if it is understandable (usable) by the consumer or other user. We should not overlook the potential of educating the public on what we already know, because it can be inexpensive and very beneficial. This effort

should be done in consortium with the development of the integrated database. It is not necessary to collect additional information before we proceed with the educational effort, but as we progress with the data and data collection systems, we also need to move forward on the educational front. There are probably low-cost methods of pathogen reduction that are already known to be effective. In many cases, these methods are simply good management practices that should be used currently, but producers and consumers have not been clearly informed about their benefits. Also, there may not be economic incentives that encourage their use.

The focus on the effort that is needed to associate farm management strategies with pathogen levels is noteworthy and needs to be pursued. For many onfarm pathogen reduction practices to be effective, the food channel must be structured so that there is less chance of cross-contamination further up the food channel once the pathogen levels have been reduced at the preharvest or farm level. Cross-contamination can occur through commingling of livestock and livestock products, through the introduction of pathogens into the food channel by workers, and in other ways.

As Hueston and Fedorka-Cray state in their paper, "The challenge remains to identify each of the numerous databases, characterize their unique strengths, and incorporate their information to evaluate the role of farm management strategies for ensuring food safety at the production level." This concisely summarizes the focus needed in this area. We must recognize that there already are many data available for use and analysis. When a new study was undertaken in the past, new data were usually collected as part of it, with little thought given to the information already available, and even less thought given to coordinating multiple studies with a common focus and need for similar data. This lack of planning and foresight caused duplication of effort and funding. Coordinating these efforts requires much upfront planning, but we must quickly begin to address these issues, because in the future resources will be decreasing. A common theme throughout this conference is that when an integrated data system that would fit into food safety analysis is developed, the developers should first and foremost think about who the potential users will be, what their needs are, and how the integrated system can be made user-friendly.

We must reevaluate the possibilities of developing "branded products" with certain food safety or quality attributes. This would involve developing products that consumers could identify as higher in quality and meeting certain food safety standards, and for which they would expect—and be willing—to pay more. These quality attributes might include such things as low levels of

pathogens or freedom from residues. The feasibility of such branded products for domestic and foreign markets needs to be evaluated. There may be many opportunities here that have been overlooked. The pork production industry already has the Pork Quality Assurance (PQA) program, which focuses on quality. A primary focus of the PQA program, as currently practiced, is residue reduction or control. This type of program could be expanded into the area of food safety attributes. It may be possible to determine whether strategies in areas such as production/management, packing, processing, and handling lead to lower pathogen levels. As part of the requirements for these branded products, certain production, packing, processing, and handling procedures could be stipulated. Another way of ensuring product quality might be to identify the origin and health status of herds or flocks prior to slaughter. This was proposed in the paper by Buchanan, Acuff, and Halbrook, where the possibility is discussed of identifying high-risk animals and separating them from low-risk animals during packing and processing.

The idea of the branded product raises the subject of identifying the demand for food safety. Recent studies at Iowa State University and elsewhere have shown that consumers are willing to pay for enhanced food safety, which means higher quality food and food products. Nevertheless, although it may be technically feasible to reduce pathogen levels to near zero, consumers probably would not want to pay the cost. The bottom line is that for industry-level HACCP analysis, it is necessary to evaluate both the cost of the HACCP program or of strategies in the HACCP program to reduce the level of pathogens in foods, and the actual or perceived benefits from reduced pathogen levels. Much of the work to date has focused on the supply rather than demand side of improved food quality. An overriding theme in the HACCP system analysis should be cost-effective production of high-quality food (see Hueston and Fedorka-Cray).

HACCP System Analysis

A truly successful HACCP system analysis identifies management, slaughter, processing, and distribution practices that reduce pathogen levels and thereby the number of pathogen tests needed. Initially, it is a data- and testing-intensive effort. If successful, however, the way that HACCP systems are evaluated and implemented may change. One possible change is a shift in orientation of HACCP program surveillance from animals and products to processes. Initial efforts in HACCP analysis, if successful, will identify the different management strategies, processes, and the like throughout the food, meat, and meat product chain that are most effective in

pathogen reduction. Once this happens, the HACCP system can gravitate to more of a surveillance of the industry to ensure that those practices are actually being used, so the amount of individual meats and meat products that are tested for pathogen levels can be reduced. Although testing will still be needed, it will have a different focus.

The development of computer capabilities over the 10 to 20 years has greatly expanded the profession's ability to model events. In several instances, the ability to develop models has outstripped the data and their quality available for use in the models. One of the underriding issues of this very conference is that adequate or appropriate data are unavailable for food quality systems analysis. Models have been developed that are now hunting for data or ammunition for their effective use. Often, the problem is not *insufficient* information, but rather the *wrong type* of information for use in systems analysis.

A key conclusion of this conference is that we need an integrated database for cost-effective analysis of improved food safety and to track what happens in the meat and meat product industry. We must have key indicator variables to track industry trends over time. The industry is changing, with new methods of processing and other modifications. New methods can cause new problems in the industry.

Another item that is beyond the scope of this conference, but needs serious consideration, is that many professional groups, universities, Federal agencies, and other entities are not structured for effective systems analysis research, and have functioned more reactively than proactively in the past. In some ways, we have not been forward-thinking enough. In other ways, multidisciplinary or systems analysis work has not fit the structural organization of these groups. Universities and Federal agencies have been structured as departments, which tend to have a specific disciplinary focus and can have difficulty functioning in a multidisciplinary setting. This is one factor that has led to the development of research centers that are located at universities and other institutions.

The food safety profession (really all professions) must develop a more integrated, forward-thinking approach as it looks at problems and issues of the future because they cut across many different disciplines. Research programs also need a more multidisciplinary focus. Additionally, systems-level analysis should be recognized for the benefit that it is providing to society. There has been a tendency for highly specialized or component work to be more widely recognized and accepted professionally than multidisciplinary systems analysis work. The very existence of this conference is a clear indication that there is change. This change must continue and accelerate.

Discussion from Audience

Discussion first focused on the critical points for pathogen reduction in the meat and meat product channel. It was pointed out that some of these points may be at the packer level, rather than the production or management strategy level. The sheep industry in New Zealand was given as an example, where it was shown that the most important factor for the introduction of pathogens to carcasses was the condition of the wool at slaughter—whether it was clean or dirty, wet or dry. While pathogen entry at the packer and processing levels was to be addressed in another session of this conference, the question itself pointed out precisely the reason why a systems analysis is needed to study the food safety and quality issues. It is necessary to address pathogen entry points at each level in the processing/handling chain. Different issues that can be addressed with respect to pathogens are pathogen reduction or food quality as an entity unto itself, and cost-effective production of high-quality food.

Additionally, some pathogens affect production efficiency at the animal production level. This again emphasizes the need to evaluate the pathogen level at all stages in the food chain to identify key critical points for pathogen reduction and economic benefits from that reduction.

Another discussion focused on the statistical techniques available, such as Bayesian techniques, that can be used when sparse data are available to generate some fairly realistic and highly usable results. This is particularly the case in a number of food safety issues where the data may not be available or in the form desired. However, much can be done with available data by using appropriate statistical approaches.

An additional issue was that there should be more focus on methods that reduce fecal contamination of carcasses. There is some work going on in this area, and a fair amount is known about contamination of carcasses by fecal materials.

It was also pointed out that when scientific information is available, it must be used appropriately and accurately, and infused into the decisionmaking process. Some remarked that there is a tendency to establish regulations that may be politically appealing but ineffective for resolving actual problems.

Different livestock species groups must focus on several pathogens, not just one. There has been a tendency in the past to focus on just one or two pathogens, when, in fact, several pathogens should be tracked to truly follow industry trends. This would alert the industry to new pathogens that may not be a problem now but are

growing, and would allow the industry to make adjustments before they truly become a problem.

Another issue that surfaced was the lack of data available for home food preparation. It is quite difficult to obtain this type of data, but it is important because food pathogen problems can stem from improper preparation and handling of products prepared in the home.

The variability of pathogen levels was discussed. Studies have shown that while there is variability in pathogen levels within a plant, it is much less than between plants. Available information shows that intervention seems to be working in the industry. Some plants tend to have low levels of pathogens in their meat and meat products, whereas others have much higher levels of pathogens in their products. Industry experience should be captured as an expert opinion type of research. This type of approach to collecting information is quick.

It was also pointed out that seasonal variation in pathogen levels should be considered in pathogen-level studies.

There was discussion on the line of responsibility along the food chain continuum. All stakeholders in the industry need to accept their responsibility in producing safe food in a cost-effective manner. This includes everyone from the input supplier to the producer, from the processor to the distributor and to the consumer who prepares the food at home. A breakdown at one point in the continuum can cause major problems for the entire industry.

Summary

This conference has made it clear that food safety issues cover the entire food industry continuum. A global view should be taken in developing the food safety agenda, a view that supersedes single sectors and particular interests, and demands a multidisciplinary focus. Data collection efforts, too, should be coordinated and multidisciplinary.

The industry can use economic incentives to implement effective HACCP systems. Respondents generally felt that this is beginning in the industry, and that premiums can be extracted from the market. However, for development of effective premiums, there will need to be accurate animal, meat, and meat product traceback within the market, so that individuals who cause increased pathogen levels will not receive a premium, but rather a discount—they may be asked to pay for any damage to the industry. The food production and marketing system should be configured to reward participants who improve

food quality. There must be better feedback and trace-back mechanisms that allow identification and bestow rewards or penalties. Although the system is moving in this direction, there is room for improvement.

A goal of the food production system is to produce a food supply that is as safe as technically possible and that is also economically feasible. Critical control points for key pathogen entry into the food system need to be evaluated for amount and cost-effectiveness of pathogen reduction. This implies cost-effective pathogen reduction research and cost-effective data collection.

Risk Assessment for Foodborne Microbial Hazards[1]

Tanya Roberts
Economic Research Service, U.S. Department of Agriculture

Alwynelle Ahl
Robert McDowell
Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Introduction

Eating food, drinking water, and breathing air are three of the most intimate interactions between human organisms and their environment. Living and nonliving agents from the outside are taken into the body and then literally incorporated as part of the body. This intimacy is absolutely necessary for survival, yet it is not without risks. Many chemical and biological agents reside in the environment or in the body of other animals or humans that can damage the human body when inhaled or ingested (table 1). These agents typically cannot be seen, smelled, tasted, or identified by touch. Rather, they are recognized by their effects on humans. Because what may be pathogens or toxins for one species may not affect another, reliable animal sentinels are difficult to find.

To survive such risks in ancient times, potentates used official tasters as sentinels to test the safety of food and drink. More recently, prisoners have served similar purposes for human experimentation with pathogens. In today's more ethically sensitive times, human populations have become their own sentinels for food safety. Because of this, monitoring and surveillance of foodborne illnesses is a particularly important part of food safety.

In societies where people raise and slaughter their meat animals at home, each family group is responsible for the safety of their food. In larger communities, slaughtering and butchering are community activities. Without refrigeration, these industries remained local and the local communication network ensured that healthy animals and good sanitary procedures were used. With the onset of refrigeration, meat and poultry markets became national and international. Food production and processing became separated occupationally, spatially, and temporally from the consumer.

Farm management practices resulting in trichinae in U.S. pork bellies led to the closing of some export markets in the 1880's. This influenced the passage of the 1890 Act,

Table 1—Potential pathways of human exposure to animal diseases

I. Direct contact with live animal
   - Animal bites
   - Contact with the animal's skin, fur, tail, and the like, and with the microorganisms found there

II. Indirect contact with the live animal
   - Aerosol contamination of the barn and air system
   - Contamination of the walls, floor, gates, and the like
   - Animal refuse
   - Flies or fleas biting the infected animal and then biting humans and transmitting disease

III. Direct contamination by the carcass
   - Some organisms penetrate the skin of the personnel handling the meat
   - Entry of organisms through cuts and nicks on the hands of slaughterhouse or processing plant workers

IV. Indirect contamination by the carcass
   - Aerosol contamination when the carcass is cut up and/or slapped onto the counter, thereby releasing pathogens
   - Contact with knives, wiping clothes, sinks, and the like where pathogens have been deposited

V. Cross-contamination of other edible products
   - Carcass contaminates other carcasses in the slaughterhouse
   - Meat products in the processing plant
   - Other raw or cooked foods in the kitchen of a private home or commercial feeding establishment

VI. Consumption of meat, poultry, egg, and dairy products

Source: Adapted from Roberts, 1986.

which implemented the inspection of exported meat products. Outrage over the conditions in slaughterhouses that processed meat for domestic consumption led to the Meat Inspection Act of 1906. These acts resulted in a process of organoleptic inspection of live animals and their carcasses and organs, using the informed senses (sight, smell, touch) by veterinarians and other trained inspectors. This became the primary method of ensuring safe and wholesome food of animal origin. Recently, the National Academy of Sciences (National Research Council, 1985) has emphasized the importance of using new technologies and scientific capabilities in the food safety domain. More recently, other groups have advocated using risk assessment as an adjunct in food safety activities (Council for Agricultural Science and Technology, 1994).

New sophisticated laboratory tests have created additional options for detecting unwanted pathogens. (Although their use is controversial, note the court battles over the Food Safety and Inspection Service (FSIS) requiring *Escherichia coli* O157:H7 testing in beef.) Improved analytical tools for risk assessment of reproducing organisms have been developed. These new analytical techniques and tests provide useful tools for studying the best ways to evaluate the safety of food of animal origin through each link in the food chain (figure 1). The challenge is how to most effectively and efficiently use these tools to help assure the safety of food of animal origin (Ahl, 1994).

The "links in the chain" metaphor is an important one for several reasons, and because it stands in contrast to the more usual metaphor of the "food safety continuum," it is meaningful to briefly contrast the two. The food safety continuum emphasizes the fact that animal health on the farm and inputs into that process follow through the continuum and can become hazards at the point of consumption. This is an important concept that reminds us that many of the ultimate agents that compromise our food supply come from food animals. The image of continuity is apt and powerful. However, in order to dissect the complex series of events from farm to table into smaller, more manageable chunks, it is useful to think of the continuum as a chain made of smaller links (figure 1). Each link is connected to another in a series, and represents a set of closely connected events that affect the ultimate outcome of human health (table 2). Isolating these links in the chain can focus thinking about the events that occur within each link, as well as direct attention to the connections between links.

Food Safety: Links in the Food Chain

To identify where pathogens are entering the food chain, it is important to break the food chain into its component parts or links. These links represent significant stages in

Links in the food chain.

The food chain is a continuum from farm to human health outcome. However, this continuum is divided into links of specialized activity that are self-contained, yet connected as part of this chain.
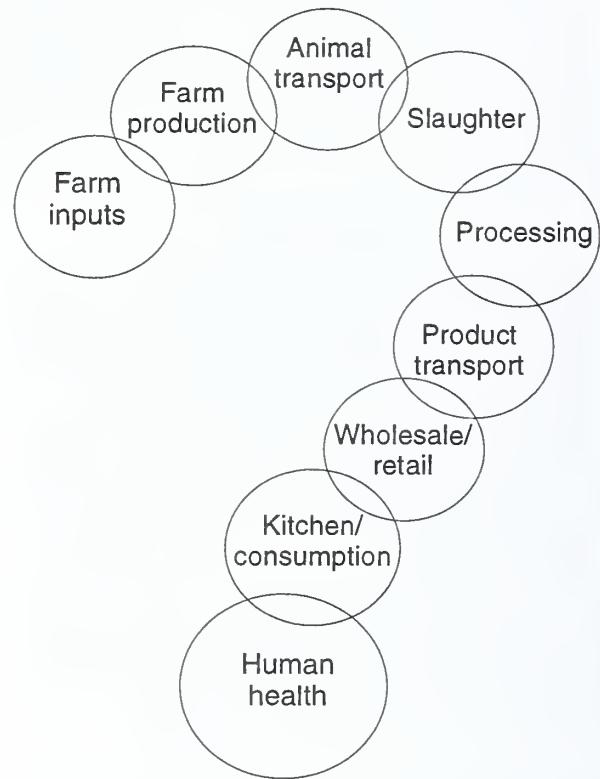
food production, handling, and consumption where high-risk practices may be identified (table 2). Farm inputs may bring pathogens onto the farm. Farm production practices may reduce or amplify pathogen numbers, as well as bring new pathogens into contact with food animals where they cause animal disease or cause animals to be carriers for human pathogens. The stress of transporting animals to slaughterhouses often causes increased shedding and spreading of pathogens among the animals. Slaughtering procedures can minimize or amplify the spreading of pathogens among animals, carcasses, and cuts of meat.

Processing and product fabrication can introduce new pathogens from worker handling, ingredients, and water used in processing; existing pathogens may increase in number. Although parasites and viruses do not multiply in meat, bacterial pathogens can multiply at room temperature in or on nutrient-rich animal products. Ground

products with their large surface area are particularly good growth media at room temperature. Some bacteria, such as *Listeria, Yersinia, Aeromonas,* and *Clostridiumbotulinum* type E, can also grow at refrigeration temperatures.

Transporting meat products to wholesale/retail operations may permit pathogen growth, cross-contamination of products, or introduction of new pathogens. How foods are stored and displayed affects pathogen growth through

Table 2—Variables of potential concern in estimating foodborne disease risks in beef production, handling and consumption

Farm input use	Farm production practices	Animal transportation
Production animal: Animal breeds (e.g., Holstein, Hereford), animal purpose (dairy, beef, veal), gender, age.	**Type of operation:** Product (e.g., dairy, veal calf, grow-out, finishing, feedlot, range-fed beef), vertical integration (owned, contract, independent), and purchased and/or farm-produced feed.	**Transport type:** Independent trucker, company truck, and/or railroad car, ship, plane.
Type of housing: Open range, feeding shed, group pens, individual calf housing, enclosed barn for all animals (concrete/wood/dirt floor), etc.	**Herd management systems:** Calving management, calf rearing management (e.g., weaning practices), breeding practices, replacement strategies, barn cleaning practices.	**Travel:** Length (local/regional/national/ international), timing season. **Feeding system:** Feed and water practices during transit.
Feed inputs: • Use of colostrum (fresh or frozen) fed to newborns and protective effect against pathogens (amount fed, timing of feeding). • Calf feed type (udder or pail milk, formula, milk replacer). • Other types of feed (pelleted feed, roughage, additives, silage, etc.) and treatment of feed (irradiated, steam sterilization, medicated). • Use of pasture, rotation, and manure management on pasture.	**Feed handling:** Delivery system (bulk feeding at-will, computer-programmed rations), types of rations/roughage, additives (rumensin, vitamins, antibiotics, idophones), and cleaning of system. **Animal health practices:** Herd health monitoring, use of veterinarian services, source of drugs and drug-use patterns.	**Manure handling:** Loading procedures, stanchions in transportation, number of layers of animals. **System cleaning:** Type of cleaning, location, and timing of cleaning of transportation vehicles. **Identification:** Maintenance of animal identification.
Water sources and access: Well water, municipal water supply (chlorinated, filtered, etc.), on-farm pond, irrigation water, manure lagoon.	**Pathogen testing:** Use of pathogen test information from the individual/herd in farm management and to support probability modeling; quality of test information (sensitivity/specificity, sampling design, frequency/breadth.)	
Wildlife access to farm: Rodents, birds or other animal access to farm ponds, food animals, and pathways to contamination (aerosols, urine, feces; ingestion of vermin).	**Water delivery:** Delivery system (pipes, troughs, etc.), testing for pathogens, and cleaning of system.	
Geographic factors: Local climate and pathogen survival, local wildlife vectors, and trade patterns/impact on replacement stock and pathogen probability.	**Manure handling practices:** Type of system (open pit, other liquid, dry, free range), disposal, and cleaning of system; animal exposure to manure.	
Pathogen testing: Testing farm inputs and the environment to identify pathogens (test sensitivity, sampling design, and frequency and breadth of pathogen testing).	**Wildlife control:** Pest surveillance and control (e.g., traps, poison); presence or absence of cats.	
	Control of visitors/trucks: Restrictions on truck/human entry.	
	Animal identification system: Maintenance of animal identification.	

temperature control, possibilities for cross-contamination, and length of shelf-life. How food is handled in the kitchen affects the probability that pathogens multiply, cross-contaminate other products, or are killed via thorough cooking. Consumer choice and behavior in storing and handling food is the last link in the chain.

The complexities of the food safety chain are exacerbated by such natural events as the appearance of new pathogens and changes to existing ones. Zoonotic agents may be pathogenic for humans but not for their animal hosts; therefore, assessing the health of the live animal may not indicate if it is carrying human pathogens. Human

Table 2—Variables of potential concern in estimating foodborne disease risks in beef production, handling, and consumption—Continued

Animal slaughter system	Beef processing system	Product transportation system
Type of operation: Integrated with processing or farm operation, single/multiple types of animals slaughtered, single/multiple slaughter lines.	**Type of operation:** Integrated with slaughter or retail operation, single/multiple types of products/animal species processed, single/multiple processing lines.	**Transport type:** Independent trucker, company truck, and/or railroad car, ship, plane.
Antemortem treatment: Live animal inspection, hide wash, dry manure removal from animal.	**Cross-contamination control:** Physical separation of incoming trucks/personnel that may be contaminated from plant workers and product; equipment cleaning program, knife sterilization, worker glove use/handwashing, and refraining from handling food when ill; air ventilation system; separation of raw from cooked products; special control procedures for ground (comminuted) products.	**Length of trip:** Local, regional, national, or international movement of raw or cooked product.
Carcass preparation: Hide removal, opening of abdominal cavity, tying off digestive tract, and other procedures to minimize manure contamination of meat.		**Temperature control:** Refrigeration practices during transit, temperature monitoring, use of temperature indicators.
Cross-contamination control: Plant air ventilation system; physical separation of product/workers from beginning to end of line; equipment cleaning and/or sterilization between carcasses (e.g., knives); worker glove use/handwashing; and refraining from handling food when ill.	**Meat cutting/trimming:** Removal of fecal contamination; minimization of cross-contamination along the processing line and from workers to product.	**Cross-contamination:** Requirements for driver's hygiene; sanitary handling practices.
Digestive tract removal: Minimizing spillage on meat, organoleptic examination of organs.	**Meat temperature control:** Control of meat temperature during fabrication, cooling of processed products, and temperature maintenance after processing.	**Cleaning system:** Type of cleaning, location, and timing of vehicle cleaning.
Carcass treatment: Removal of fecal contamination and minimization of cross-contamination among carcasses and from workers. Carcass cooling and temperature maintenance.	**Inventory control:** Special date control programs for ground (comminuted) products and for cooked products, and coordination with lot identification system for products.	**Pathogen testing:** Testing vehicles, raw product, processed product, and environment for pathogens.
Plant sanitation program: Weekly/daily/shift/lot schedule for cleaning building, drains, and equipment.	**Plant sanitation program:** Weekly/daily/shift/lot schedule for cleaning building, drains, conveyor belts, grinders, and the like.	**Identification:** Maintaining lot and company identification.
Pathogen testing: Testing animals, equipment, the environment, workers, and meat for pathogen occurrence.	**Pathogen testing:** Testing raw meat, finished product, equipment, workers, and the environment for pathogens.	
Identification: Maintaining farm/carcass/lot identification linkages.	**Identification:** Maintaining slaughterhouse/lot identification linkages.	—Continued

activities add to the complexity too. Consumers seek novelty in foods, which leads to the development of new food processes. This may result in foods with new pathogen profiles. Proper procedures in cooking and handling food in the kitchen at home are not understood well. Food preparation jobs in institutions are often low-paying, which leads to rapid turnover, further complicating the proper training of food service workers.

Risk Assessment in Food Safety

Risk assessment is the science of understanding hazards (unwanted events), how likely they are to occur, and the consequences if they do occur. The answer to the latter two questions is defined as "risk" (Ahl et al., 1993). However, as in all new fields, the nomenclature is often confusing and ambiguously used. For example, the term

Table 2—Variables of potential concern in estimating foodborne disease risks in beef production, handling, and consumption—Continued

Meat wholesale/retail system	Kitchen handling/consumption	Food link to human health
Type of operation: Degree of integration with processing and food preparation activities.	**Type of kitchen:** Home, restaurant, fast food chain, schools, group homes/elder care, military, detention facilities, and the like.	**Surveillance and monitoring:** Foodborne association is variable depending on the pathogen/food combination and whether the illness is caused by cells or their toxins. Improved monitoring and surveillance combined with epidemiological investigations using new tests can link disease outbreaks to causative pathogens/food.
Cross-contamination: Physical separation of plant workers and product from incoming trucks/personnel that may be contaminated; equipment cleaning program; knife sterilization; worker glove use/handwashing; air ventilation system; separation of raw from cooked products.	**Cross-contamination:** Kitchen sanitation (washing utensils, counters); glove use/ handwashing; separation of raw from cooked products; refraining from handling food when ill.	
Product fabrication: Minimization of cross-contamination from raw to cooked product, among products, and from workers to product. Risk level may vary depending upon fabrication practices (origins of meat used in ground product, age of pieces, location of grinding, number of regrindings), and reworking practices.	**Temperature control:** Rapid refrigeration after purchase and maintenance at low temperature. Cook raw animal protein products well-done.	**Acute illness:** Variable incidence for various chronic illnesses and variable severity distribution, depending on the pathogen and food combination.
	Inventory control: Use of raw product within a few days, especially ground meats.	**Chronic illness:** Human-to-human transmission is variable, depending on the pathogen and food combination.
Temperature control: Control of meat temperature during fabrication, cooling of fabricated products, and temperature maintenance after processing.	**Pathogen testing:** Testing raw meat, finished product, equipment, workers, and the environment for pathogens.	**Secondary cases:** Variable, depending on the pathogen and food combination.
Inventory control: Special date control programs for ground (comminuted) products and for cooked products, and coordination with lot identification system for products.	**Consumption:** Avoid ordering undercooked beef, sending restaurant food back for more cooking if not well-done.	**High-risk individuals:** Increased risk of acute illness, more severe illness, and chronic illness in immunocompromised and other individuals. Variable, depending on the pathogen and food combination.
Sanitation program: Weekly/daily/shift/lot schedule for cleaning knives, grinders, display cases, drains, and the like.	**Identification:** Source of product.	**Outrage factors:** Variable, depending on who is at high risk, the pathogen/food combination, the ability to control the pathogen using a variety of risk-reducing techniques, and the like.
Pathogen testing: Testing raw meat, finished product, equipment, workers, and the environment for pathogens.		**Anticipating the future:** Improved knowledge about evolving foodborne pathogens and human illness, especially linkages to chronic disease.
Identification: Maintaining lot/company identification linkages.		

"risk" is informally used to refer to the hazard itself, the probability of an event's occurrence, or to any behavior or activity that could bring harm to an individual. Risk assessment is the domain of the sciences, and uses concepts from many fields: epidemiology, pathology, virology and bacteriology, physiology, biochemistry, nutrition, probability, systems analysis, decision theory, and others. Risk assessment also utilizes information such as anecdotal evidence, expert opinion, and other items from less structured sources. However, the evidence used in a risk assessment and the sources of that evidence must be displayed so that there is no ambiguity about the kind of information used in the analysis. The pertinent information is structured to assist the risk manager in making a decision about mitigating the likelihood or consequences of the adverse events.

Risk management is the domain of the decisionmaker who chooses among courses of action, the acceptability of the risk posed by each, and the use of mitigation measures to decrease the risk. Larger spheres of policy, diplomacy, politics, economics, and legal issues are also part of risk management. It is important to remember that the risk assessment process is initiated by risk managers, who utilize the output in making decisions.

At minimum, the requirements are that risk assessments be transparent, flexible, documented, and used consistently. As new data become available, the risk assessments must be updated. Risk assessments then become powerful analytical tools that can support good decisions and promote food safety in production on the farm, in processing, and all the way to the presentation of food at the table. Because data needs and models used for risk assessment are closely related, a discussion of models that may be useful in food safety risk assessment is important to considering data needs for microbial food safety. The importance of risk-assessment models is that they help standardize approaches and define data needs, and allow the quantitation of risk and uncertainty. With increasing sophistication, the biological variability inherent in both pathogens and the humans they attack may also be modeled (Frey, 1992). Models and the risk assessments developed from them can best be generated with input from all interested communities: scientists, businesses, regulators, and consumers. This interaction initiates the process of risk communication. Properly conducted risk assessment assures that the decision-making process is open to scrutiny by all who are affected by the decisions.

Many fields use risk assessment. For many years, engineers, financial analysts, insurance companies, economists, and others have used a variety of risk assessment methods. These methods encompass qualitative, semi-quantitative, and quantitative approaches. One of the most

familiar models is the one presented in the 1983 "Red Book" (National Research Council, 1983), which consists of four steps: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. The process was designed to characterize the potential adverse health effects of human exposure to environmental hazards; it was designed to be used as a tool in environmental and human health management. The model has been widely used in many parts of the Government and in many regulatory activities. This model may be useful for assessing risk at the time food is eaten, because dose-response and exposure assessment can help evaluate more immediate outcomes at the consumer level. The four-step method may prove useful in evaluating certain pathogens such as viruses, parasites, and other agents that do not reproduce after the host has been slaughtered.

However, for bacteria in the food safety chain, the four-step model may not be as useful as others. One reason is that the "dose" of pathogen, for example, in an animal on the farm may be very small, existing at a level that is undetectable by current testing methods. Husbandry conditions during transport to slaughter may favor the growth or shedding of a particular pathogen and its eggs, cysts, or larvae in an animal's gastrointestinal tract so that when the animal arrives at slaughter, the pathogen is an important component in the animal's feces. If these fecal bacteria contaminate the meat, they may propagate through the food chain, and eventually they or their toxins may affect human health. *E. coli* O157:H7 and *Salmonella* are examples of fecal bacteria that may replicate in food. Thus, in tracking foodborne pathogens through the links of the food chain, an agent that replicates may require a different approach from those for which the "Red Book" model was developed. Much of current discussion about food safety centers primarily around agents (e.g., bacteria) that reproduce.

Reproducing microorganisms make risk assessment challenging. For example, only one or two microorganisms on a very large piece of food may be undetected. However, to assume that there is no risk when no microorganisms are detected is not appropriate. In only a few hours or days, under appropriate conditions, replication can occur and what was undetectable is now sufficient to cause illness. Typically, each model includes information about the potential for colonization and growth of the microbial agent as part of the evaluation.

It is important to remember that even if food leaves a processor in sterile packs or cans, it can be contaminated by the pathogens carried by the food preparer. Thus, there is truth to the statement by Potter and Brudney (1994) that "levels of contamination on the dinner plate may bear little relation to data obtained at the time of

slaughter or even in the kitchen before cooking." Once again, emphasis on humans as sentinels for the safety of their own food is recognized.

Different risk problems require different methods. In this paper, we discuss a powerful tool, probabilistic scenario analysis (PSA) and its close relative, fault tree analysis (FTA), and demonstrate how they can be applied to the analysis of microbial hazards in the food chain.

Probabilistic Scenario Analysis

The first use of probabilistic modeling as a research tool, in its modern form, stems from work on the atomic bomb with techniques developed by Ulam, von Neumann, and Fermi (Hammersley and Handscomb, 1964). In the 1950's, Hermann Kahn of RAND Corporation used the concepts of PSA to evaluate the "what if" scenarios of nuclear proliferation (Cooke, 1991). By 1960, the powerful PSA was in use for financial analysis (Hertz, 1964), engineering applications (Rasmussen, 1981), and general economic evaluations (McKean, 1958). The method has been well tried and proved useful in many fields, including plant and animal health (Kaplan, 1993; Miller et al., 1993; McElvaine et al., 1993). It is an excellent tool for estimating the probability or frequency of an unwanted event's occurring.

PSA Methodology

The first step in PSA is to identify the hazard of interest. For purposes in this paper, these are pathogens or toxins that may occur in food and cause illness in humans who consume that food. In general, a PSA will be developed for each pathogen of interest, since the pathways affecting humans may be different for different agents.

The second step is to state the question to be investigated for the pathogen of interest. This question may lie within a single link of the food chain or it may involve two or more links. For example, one may be interested in the likelihood of *Salmonella* occurring in cattle that are ready to be sent to slaughter. This would require a look at farm input and on-farm factors related to the occurrence of *Salmonella*, modeling that includes two links in the food chain. In another situation, one might be interested in how long *Salmonella* persists on carcasses through final processing in the slaughterhouse.

The next step in PSA is to develop a list of all the expected events, given an ideal situation, in which no colony forming units (CFU's) of the pathogen occur at the end of the pathway. This is called the "success" or "as-planned scenario." For example, a processing plant produces a lot of processed meat product with no CFU's.

This lot moves through channels of commerce with no nicks or tears to the packaging. It is delivered to the retail shelves with no temperature or time abuse, it is handled properly by the consumer, it is eaten promptly, and no illness results from its consumption. This series of events occurs with no deviations from the "as-planned" pathway; there are no failure events that lead to human illness from pathogens.

For each event identified that leads to the "as-planned" state, there may be failures that result in the occurrence of the identified hazard. The next step for the risk assessor is to develop an Event Tree (ET) by constructing a diagram to illustrate the events leading to the end point (EP). Figure 2 is a draft ET for the occurrence of *E. coli* O157:H7 in cattle that enter slaughter.

For this example, the initiating event (IE) is the frequency each year of cattle shipped to be slaughtered for food consumption in the United States. At node 1 on the tree, the first question asks if cattle on the farm, ready for shipment, carry at least one CFU of a pathogen. If the answer is "no," then there is *no risk* of this pathogen passing further in the food chain as introduced directly through cattle. If the answer is "yes," then there is a risk of the hazard continuing through the food chain.

At the second node, the question is whether the pathogen is detected in cattle just before they enter the slaughter process itself. Notice that in this case, the "yes" answer is the *no risk* pathway. This answer is given on the presumption that cattle with detectable *E. coli* O157:H7 infection would be removed from the immediate slaughter process. In this example, the "no" answer would continue to the EP, that is, the pathway to the occurrence of the hazard.
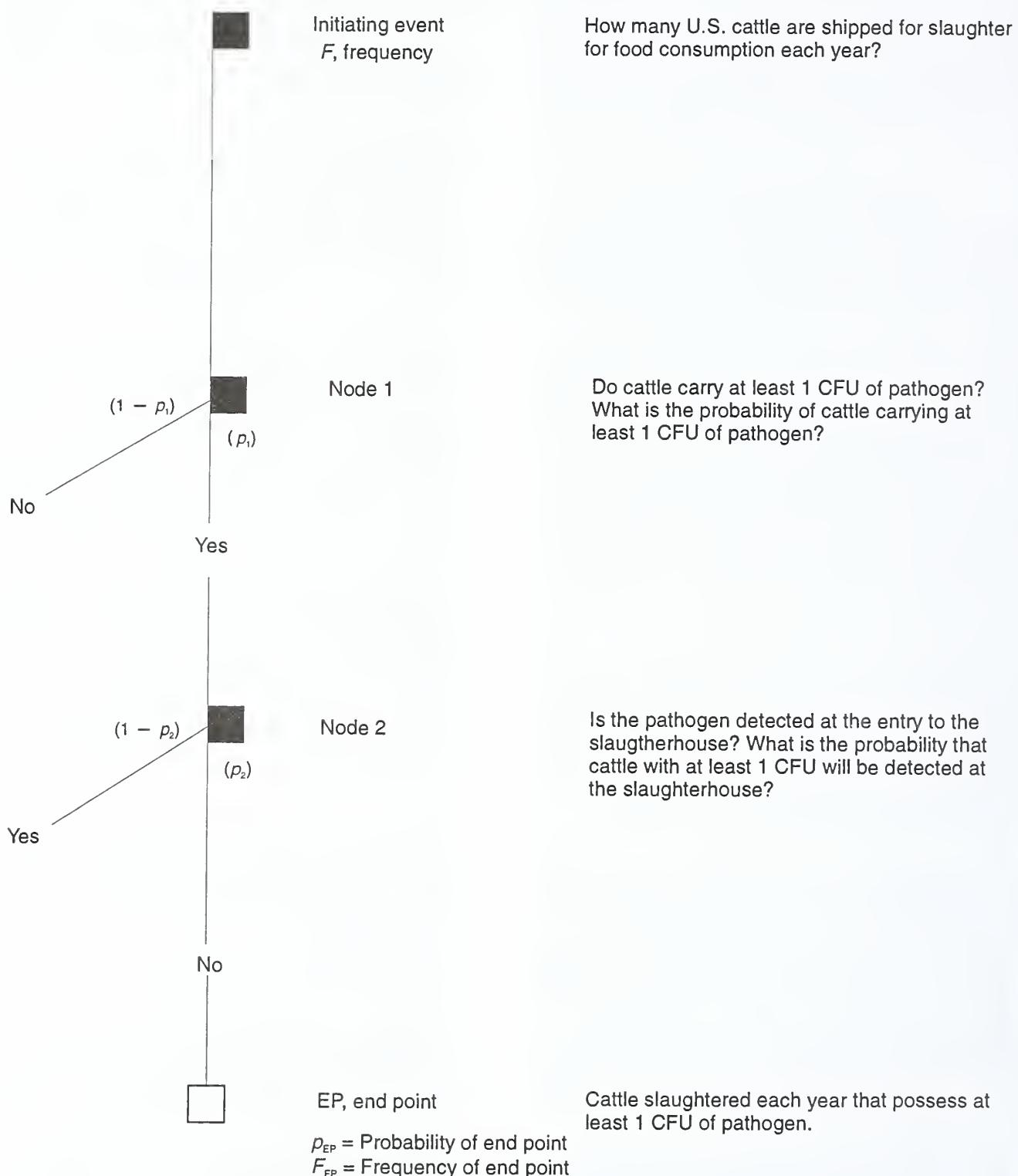
The final EP on this draft ET is "cattle actually slaughtered that possess at least one pathogen CFU." This answer may be given either as frequency or probability, as illustrated in a subsequent section discussing quantification of the ET.

Evidence for the Event Tree

Once the ET is completed, evidence must be gathered to evaluate each node in it. Each piece of evidence should be recorded and associated with the proper node; one piece of evidence may be associated with one or more nodes, as appropriate. Likewise, multiple pieces of evidence may be associated with one node. Each piece of evidence should be referenced in a bibliography so its source is documented. Labels on the ET support easy reference to the evidence and bibliographic information associated with each node.

Figure 2
A draft event tree illustrating an approach to evaluating the occurrence of _E. coli_ O157:H7 in cattle at slaughter

Initiating event
F, frequency

How many U.S. cattle are shipped for slaughter for food consumption each year?

$(1 - p_1)$

(p_1)

Node 1

No

Yes

Do cattle carry at least 1 CFU of pathogen? What is the probability of cattle carrying at least 1 CFU of pathogen?

$(1 - p_2)$

(p_2)

Node 2

Yes

No

Is the pathogen detected at the entry to the slaugtherhouse? What is the probability that cattle with at least 1 CFU will be detected at the slaughterhouse?

EP, end point

p_{EP} = Probability of end point
F_{EP} = Frequency of end point

Cattle slaughtered each year that possess at least 1 CFU of pathogen.

The next task is to describe and evaluate the evidence on the risk for each node. The evaluation of the evidence may be given quantitatively or descriptively, such as "high," "medium," or "low" risk. This allows the ET to be used in a qualitative evaluation of each node, which when considered all together, can give the assessor general feel for the urgency of a problem. Recent work from the Centers for Disease Control and Prevention (CDC) (1994) and Centers for Epidemiology and Animal Health (1994) uses a qualitative evaluation of an ET to estimate probability.

Another approach is to use an ordinal ranking system for evaluating the evidence. For example, the ranking might be 5 for high levels of risk, down to 1 for low levels. The risk level for each node on a branch of the ET can be averaged (total points divided by the number of nodes) for an ordinal estimate of the total risk for that branch.

Qualitative or semiquantitative evaluation of evidence for the ET is an excellent way to rapidly compare several problems that need attention, that is, to screen the problems (screening risk assessment). Such an approach is also useful in ranking risks for comparison purposes. When time and resources are short and a risk assessment must be made to provide guidance to a risk manager (decisionmaker), this use of PSA can quickly furnish support. However, it must be recognized that there is no definitive formal mathematical system for combining these descriptive or ordinal evaluations. Authors generally develop their own heuristics or algorithms for this purpose. In situations in which a group of experts is used to develop consensus evaluation around the evidence, the Delphi method is particularly useful (Helmer, 1969).

The same ET that is used in a qualitative or semiquantitative manner can also be quantified to provide more precise risk estimates. Returning to figure 2, it is useful now to restate the question at each node of the ET as one of probability. For example, at node 1, the question becomes, "What is the probability of cattle carrying at least one CFU of pathogen?" This probability is p_1. This is the branch that leads toward the EP of hazard occurrence. For node 2 it is p_2, and so on.

Quantifying the Event Tree

When the decision to be made is of great import or when a precise risk assessment is necessary, it is desirable to quantify this same ET for more precise analysis of the hazard in question. The evidence at each node must be evaluated very carefully. In many instances, more data or more precise evidence may be sought for this quantitation.

In developing quantitative estimates for the ET in figure 2, the probability at node 1 of cattle carrying at least one CFU of pathogen is p_1. The probability of cattle *not* carrying at least one CFU is $(1 - p_1)$. The EP of the ET can be expressed in several ways. For example, the risk assessor may wish to estimate the *probability* of slaughtered cattle having at least one CFU. This probability would be calculated using the following formula:

$$p_{EP} = (p_1)(p_2).$$

That is, the probability of the EP event occurring is equal to the product of the probability of the risk event occurring at the first node and the second node. If, instead, the risk assessor wished to express the EP in terms of the expected frequency of the event, then that would be calculated as:

$$F_{EP} = (F_{IE})(p_1)(p_2).$$

That is, the frequency, F, of the EP event (F_{EP}) is equal to the product of the frequency of the IE (F_{IE}) and the probabilities of the risk event occurring at the first and second nodes.

The ET can be populated with various kinds of data. For example, a sophisticated epidemiological survey may provide mean and standard deviations for a given event. This information, both mean and standard deviation, can be used directly at one node in the model. At another node along a branch there may be only sketchy data from anecdotal sources or a casually conducted survey; this less rigorously defined information can also be used in the model. The information is captured as a (minimum) three-point curve or a triangular probability distribution, the three points being the most likely estimate and the highest and lowest values consistent with the evidence available. This spread gives convincing clarity for estimates, for the uncertainty of each estimate is displayed as the probability distribution function (PDF). The highest and lowest values close to each other indicate a higher degree of certainty about an estimate than do those further apart, just as small standard deviations indicate more certainty than do very large ones (figure 3).

The total probability for the ET, that is, the probability of the hazard occurring, is the product of the probabilities in each node of the branch (accomplished by employing a software package such as @Risk to complete a Monte Carlo simulation). If the ET has more than one branch, the probability associated with each branch must be calculated and summed to provide the total probability estimate. The PDF can be transformed into a cumulative distribution function (CDF) that allows the risk manager to read the frequency on the X-axis and the cumulative probability of frequency on the Y-axis (figure 4).

Figure 3
Probability density functions

A probability density function (PDF) captures the entire range of the state of knowledge and displays uncertainty. Points a, b, and c are identical. If one reported only a point estimate, the information encompassed in PDF curves A, B, and C would be assumed to be identical. Note that curve B illustrates the most confidence (least uncertainty), while curve C illustrates the least confidence (most uncertainty). This kind of information can be very important to decisionmakers.
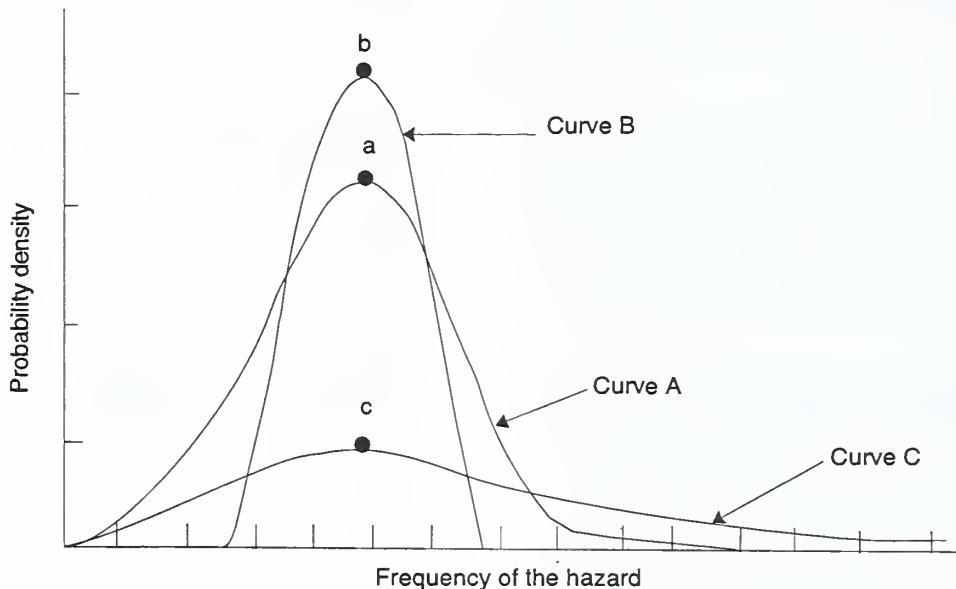
Figure 4
The PDF curve can be transformed to a cumulative density function (CDF) curve, allowing one to read probability directly from the y-axis
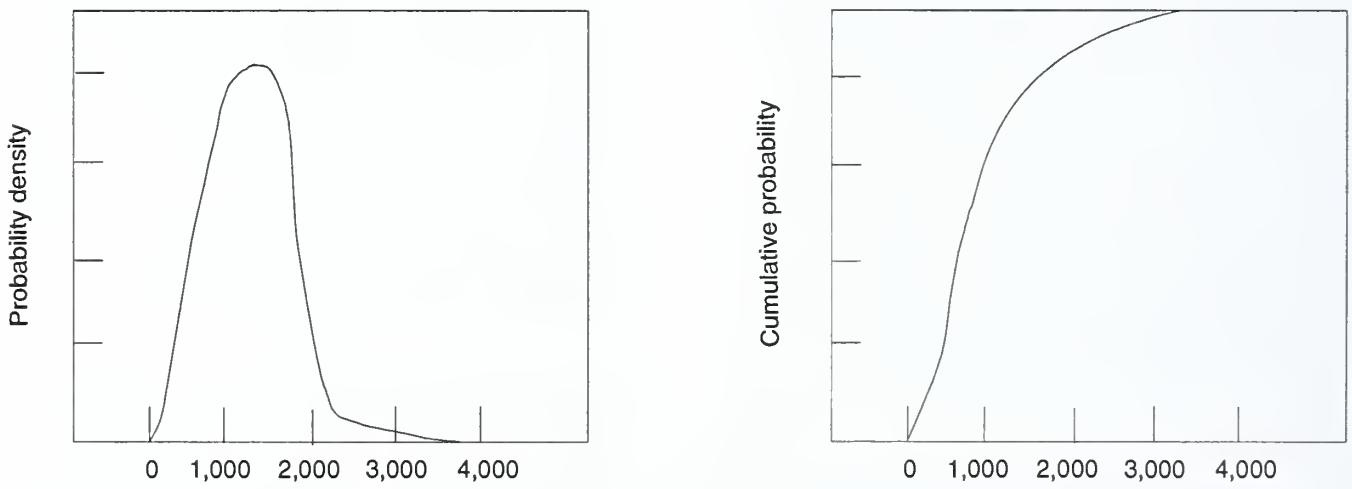
PDF— pounds of prohibited material entering Alaskan landfills annually, PDF

CDF— pounds of prohibited material entering landfills annually, CDF

Source: Modified from McElvaine et al., 1993

Fault Trees

Risk assessment of the links in the food chain can be done starting with human illness data and working backwards through the links in the food chain. In FTA, the Fault Tree (FT) begins with the occurrence of the hazard and from there, reasoning back to each of the events that could and/or must have occurred for the hazard to be present. A PSA predicts forward, whereas an FTA moves backward in time. The events are analyzed to indicate whether one and/or more events occur separately or together to lead to the failure and occurrence of the hazard. Figure 5 is an example of an FT. It traces human hospitalizations for septicemia backwards to the causative organism, perhaps *Salmonella*, to the putative food sources, possible food consumption/production practices, and so on. Septicemia, or blood poisoning, can be caused by a variety of organisms including *Salmonella*. If we start with this as the unwanted event, we can work backwards using an FT to identify pathways with a high probability of increasing the risk of septicemia.

At node 1, septicemia caused by *Salmonella*, we do not have very good information about the exact probability of occurrence. However, CDC's National Hospital Discharge Survey may have some relevant information (Steahr, 1995). At node 2, Bennett et al. (1987) estimated that 96 percent of all salmonellosis cases are related to food. At node 3, CDC data from 1973–91 (Lin et al., 1993) estimated that 9.5 percent of foodborne salmonellosis cases are due to beef. Both of these pieces of data need to be verified.

At node 4, because hamburger is a ground product that distributes pathogens throughout the meat, it is a higher risk product than cuts of beef, where pathogens are generally confined to the surface where they are readily killed by cooking. At node 5, while it is possible that gross cross-contamination in the kitchen can cause foodborne illness (for example, place a well-cooked hamburger on the platter with raw meat juices), it is probably more likely that people become ill from eating undercooked hamburgers. What the exact probabilities are needs to be determined. At node 6, the relationship between cooking time, temperature, and the level of contamination in the raw product is quantified. Most outbreaks of foodborne disease have been from hamburgers that were cooked rare or medium rare.

At node 7, some level of carcass contamination is necessary to introduce pathogens into the food chain, but it is unclear how much the carcass contributes and how much the bacterial growth during processing contributes. Certain grinding and commingling practices can lead to bacterial proliferation. A long shelf-life increases the time

bacteria have to grow. Temperature abuse can increase bacterial numbers, because bacterial pathogens generally grow faster at room temperature than at refrigeration temperatures. In the slaughterhouse, removal of the hide and digestive tract probably increases the likelihood and the magnitude of the hazard.

Basic data are needed to fully define subsequent nodes. Feed and water withdrawal during transport to the slaughterhouse may increase the probability of pathogens. Farm production practices, especially manure handling and feeding practices, may affect probabilities of pathogens. Finally, low levels of *Salmonella* may exist in some animal feeds. *The advantage of FTA, as well as PSA, is that both can help identify high-risk practices and help identify what data are needed to quantify the risks.*
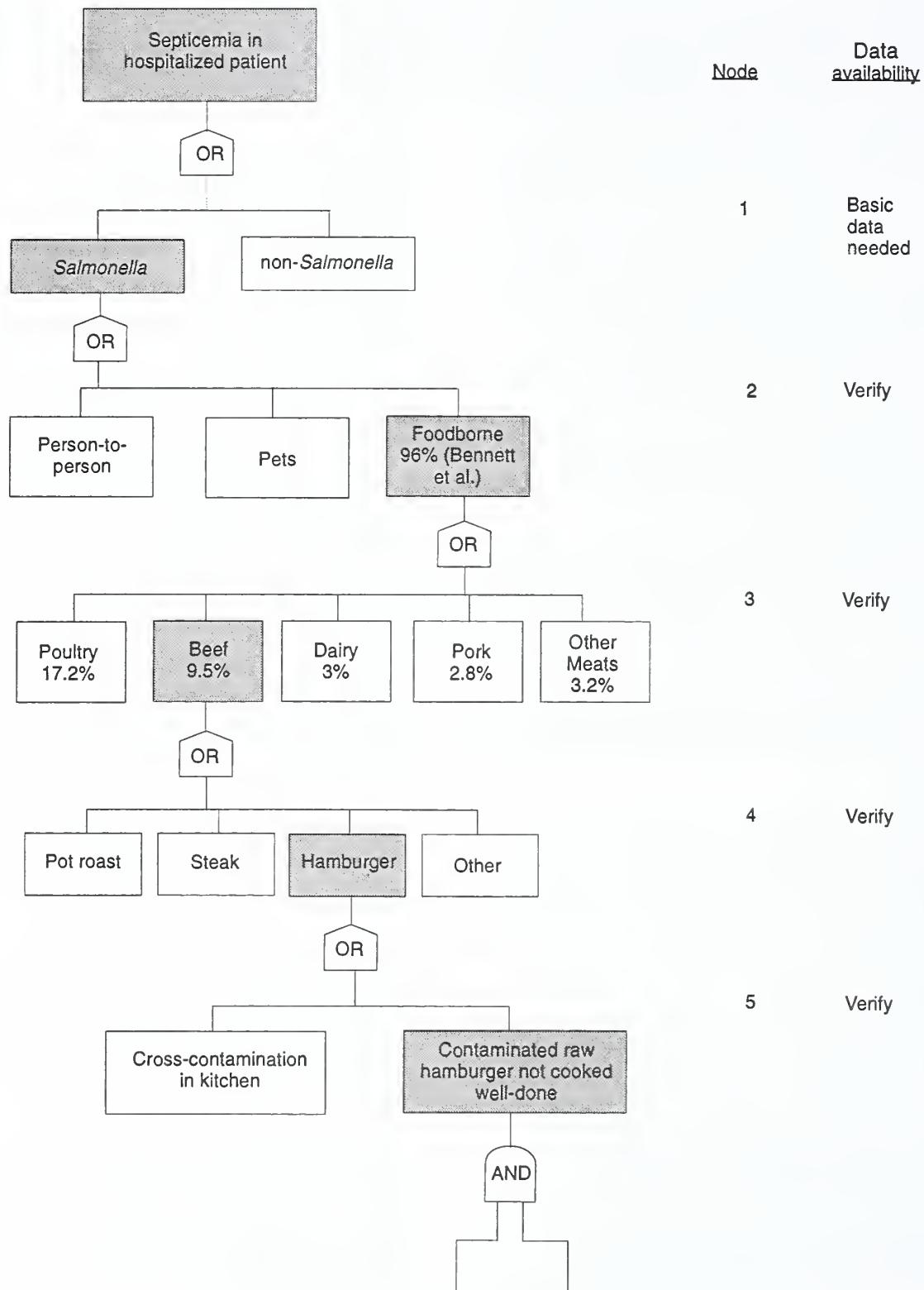
Hypotheses and Empirical Evidence

The relationships between predictions from the hypotheses (e.g., the PSA) and the empirical evidence (e.g., the human illness data) must be linked to provide feedback. This kind of feedback can provide improvements in building PSA models to make them more useful and can help in evaluating data collection methods for human illness. This kind of feedback is important not only at the consumer level, but also for animals brought to the slaughterhouse. Indeed, at all places along the food chain, predictive models and actual empirical outcomes must be used in tandem. These analytical activities are particularly important because it is ordinarily not possible to trace the meat from a single animal or group of animals from the same farm all the way to the table. This is particularly a problem for comminuted foods, such as hamburger, that result from commingling of meat items from many sources. It is just such comminuted foods that may conceal the greatest risks.

The role of empirical evidence in this entire process is of enormous importance. However, gathering empirical evidence is resource-intensive and expensive, so data-gathering must be done with careful consideration of the purpose that it will serve in supporting desirable food safety outcomes.
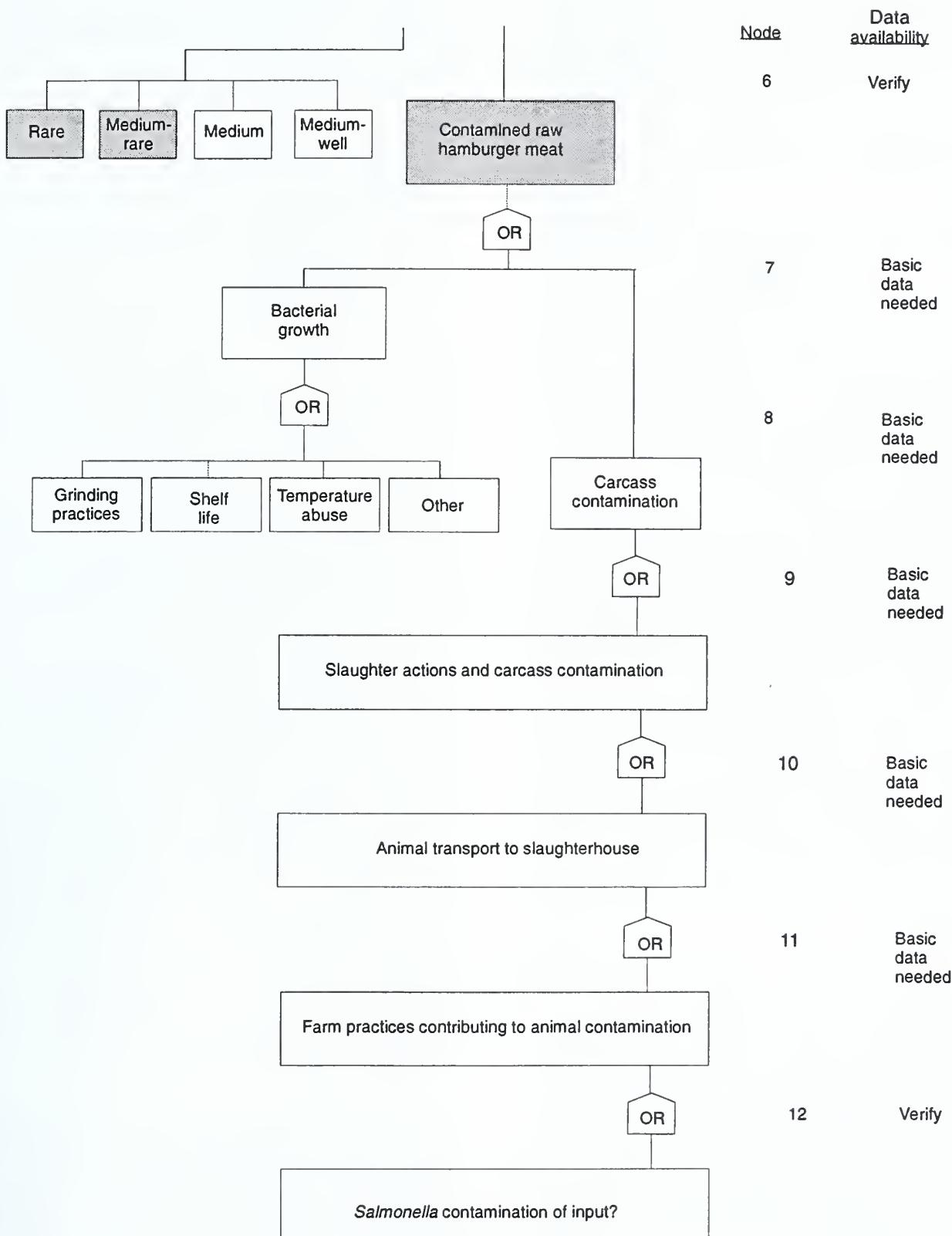
PSA with quantitative evaluation of evidence is fast becoming the "gold standard" for risk assessment in many fields. In the field of risk assessment for replicating agents, it is interesting that three different groups independently came to use this general approach. McElvaine et al. (1993) described its use in animal health-risk assessment. Rose and Gerba (1991) applied similar methodologies to water-safety risk assessment with regard to microbes. In 1994, a paper in the field of predictive microbiology described a type of scenario

Figure 5
Fault tree analysis and data requirements

Note: Shading indicates pathway of interest—perhaps a high-risk pathway.

—Continued

Figure 5
Fault tree analysis and data requirements—Continued

	Node	Data availability
	6	Verify
	7	Basic data needed
	8	Basic data needed
	9	Basic data needed
	10	Basic data needed
	11	Basic data needed
	12	Verify

Note: Shading indicates pathway of interest—perhaps a high-risk pathway.

analysis for food-safety risk assessment (Buchanan and Whiting, 1994). The use of this method for evaluating plant and animal health in importation of plants, animals, and commodities was developed working with Dr. Stan Kaplan, an engineer (Kaplan and Garrick, 1981), while Rose and Gerba, and Buchanan and Whiting worked with the ideas of Dr. Charles Haas (1981), a mathematician. Biological scientists have often followed in the footsteps of their colleagues in the physical and mathematical sciences.

PSA and Hazard Analysis and Critical Control Point Systems

Hazard Analysis and Critical Control Point (HACCP) systems can be a powerful tool for preventing food safety problems. HACCP relies on systems analysis, just as does PSA. The opportunities for combining these tools in identifying and quantifying risk and then developing appropriate methods to reduce or mitigate risk are promising (National Advisory Committee on Micro-biological Criteria for Foods, 1992).

HACCP suggests that controls for complex systems shall be concentrated in one or several places that are critical to the ultimate occurrence of the hazard. By monitoring the control points carefully, the hazard's occurrence can be stopped or at least diminished. However, HACCP does not suggest a way of identifying the critical control point (CCP) or points in the complex system. Because PSA (or FTA) lays out the series of events that must occur in order for the hazard to transpire, the quantitative evaluation of these events at each node is a way to identify potential critical points. Mitigation measures for each node along the branch(es) of the tree can be identified. Sensitivity analysis can evaluate the effect of any mitigation. The tree allows identification of places where intervention will have the greatest effect. Controls that can be instituted at the places of greatest effect and least cost are desirable.

Of great importance are recordkeeping (a data source) and testing procedures to verify that the HACCP is working and to provide data to update the PSA models. PSA and HACCP can guide the needs for data collection, yielding both efficiency and effectiveness. The process for data collection encompasses monitoring and sur-veillance at the consumer level for ultimate food safety outcomes. When evaluating preharvest food safety, monitoring and surveillance at the slaughterhouse door can serve a similar function. This provides the feedback loop that is essential to making the entire system func-tion.

An example of how PSA and HACCP have worked together in another arena may be helpful. The Eurasian pine shoot beetle (PSB) entered the United States through a Great Lakes port recently. The infestation was first identified in 1992, but by that time it had spread widely in the northern Midwest region. In Michigan, the PSB had spread through the southern half of the lower penin-sula (LP). Accelerated spread by the movement of logs (from the southern part of the State) to the sawmills in

the northern part of the LP was a concern to the Christmas tree/wreath and the nursery stock industries (concentrated in the northern part of the LP). Ultimately, forest production in other areas of the country and Canada would be affected if PSB spread, concerning a large number of stakeholders.

The State of Michigan Department of Agriculture devel-oped a list of about 25 mitigation measures that could be applied to logs moving from forest to sawmill. These mitigation measures were considered to be CCP's in this movement of logs from south to north. These measures were to be applied during four of the five seasons (early and late spring, summer, fall, and winter) that were identified as important in the PSB life cycle. The timber industry was concerned because such stringent mitigation threatened to ruin their industry. For the present, they did not see PSB as a threat to timber; indeed, it requires 20–30 years for young timber to show the effects of PSB depredation.

It was decided to ask for the support of the U.S. Depart-ment of Agriculture's Animal and Plant Health Inspection Service to discuss ways to resolve the dispute. PSA was completed for the movement of timber; it showed that 99.8 percent of the total risk of PSB colonization and spread in the uninfected areas lay in only one node of the many-branched Scenario Tree. By choosing mitigation measures to reduce risk at this node, the probability of colonization and spreading could be reduced significantly. Therefore, only one mitigation measure was chosen. Each of the 25 mitigation measures proposed by the State of Michigan Department of Agriculture was represented as a point for potential escape of the hazard, and thus was considered a CCP. However, without the careful break-down of the complex scenario, it was not possible to identify just which CCP was the most accessible to mitigation.

The approach was deemed practical by the timber indus-try, ensuring that compliance would be good. Monitoring and surveillance strategies were suggested by further analysis of the Scenario Tree so State and Federal regulators could collect data to evaluate the success of the activities. The entire process was open, and the product is transparent and easy to understand. Effective regulation resulted (Griffin and Miller, 1995). Note that the 25 measures suggested by Michigan did encompass

the one measure that was eventually selected as the best. However, without this clear and open analytic process, over-regulation without appropriate control may have been the result as compliance with multitudes of complex measures is harder to accomplish and to ensure. HACCP without the analytic guidance of PSA (or FTA) is only half of the solution.

How PSA Can Be Used in Food Safety

This approach, using PSA, can be used to predict the probability of occurrence of pathogens all along the food safety chain, within links as well as between them. It can be used to review proposed regulations (Hogue et al., 1994). It can be used to test hypotheses and evaluate the model itself. That is, does the model predict outbreaks in a way that is related to reality based on actual reports of outbreaks? Where uncertainty is very high (determined by examining the probability-density functions generated at each step of the ET), the place to concentrate efforts of research and other data gathering can be identified.

The PSA process is sufficiently flexible to represent all segments of the population and their proportional effects in estimating probability. The most susceptible populations can also be modeled separately and compared with the general population. The flexibility of this approach suggests that strategies to protect subsegments of the population can be devised and evaluated separately from those for the population at large. Using FTA developed from human illness data and linking back through the food chain to estimates developed through PSA can provide feedback for both processes.

Another use of PSA is to develop risk estimates under current conditions, and then to re-evaluate them under various new management proposals. Such assessment can support management evaluations of the best step to take next. Such clarity can also support decisions about resource use: Where in the sequence of the ET can resources be placed to get the best desired effect? It helps to evaluate resource utilization. It may also be useful in helping to identify high-risk foods, high-risk individuals, high-risk food-processing procedures, high-risk food-handling procedures, and high-risk consumption practices. Well-constructed trees that model events in the food safety chain can accomplish the goals established by Potter and Brudney (1994): "Standardize the approach; define data sources, risks and uncertainties, and expose the decisionmaking process to scientific scrutiny and public light." Public health activities for food safety may indeed become proactive rather than reactive.

Once a risk management decision is made to use certain mitigation measures, the outcome should also be evaluated. That is, the monitoring and surveillance of human health outcomes need to go hand-in-hand in order to evaluate the actual effectiveness of the mitigation/management activities (McDowell et al., 1995). This sort of feedback from outcome to assessment process is essential for the success of risk assessment in safety of food with respect to foodborne pathogens.

Estimating and Prioritizing Risks

Credible estimates of foodborne illness in the United States range from 6.5 million to 33 million cases annually, of which up to 9,000 could end in death (Council for Agricultural Science and Technology, 1994). About 40 pathogens have been identified as causing human illness via food contamination, at least in part, and advances in epidemiology and testing continue to uncover other, new "foodborne" pathogens (Council for Agricultural Science and Technology, 1994). An important question is how to set priorities for food safety interventions in such a dynamic setting. The issue of setting priorities is complex and hinges on defining food safety, comprehensively identifying all pathogens related to human foodborne disease, agreeing on how to measure the magnitude of the foodborne disease problem, identifying alternative risk control techniques and effectiveness, estimating the costs of control techniques to find the most cost-effective methods of intervening, and, finally, setting priorities based on all of these scientific data.

Defining the Food Safety Problem

The definition of which illnesses should be classified as foodborne is not clear (table 1). Acute illnesses caused by ingesting food that is contaminated with pathogens is the primary food safety problem. However, for specific pathogens, other routes of infection may be significant. For example, secondary cases of acute illness, or cases of transmission by the ill person to other family members or other children in a day care center, are generally included in estimates of foodborne disease. Less common is the inclusion of kitchen/processing plant workers who become ill by handling contaminated food. For example, brucellosis, psittacosis, and tuberculosis are important occupational hazards among slaughterhouse workers. Potential pathways for human exposure to animal diseases (table 1) also include illnesses in farm families or slaughterhouse workers who become ill because of direct or indirect contact with live animals. These farm family illnesses occur only because family members are raising the animals for food; otherwise, the family/workers would be in some other business and would not be exposed to this occupational hazard. We believe that all the cases of human illness listed in table 1 should be included in foodborne illness estimates.

The lack of complete data on disease severity is another source of ambiguity. For example, many chronic illnesses show up weeks or months after the acute foodborne infection, and it is difficult to link cases of such illnesses as arthritis, kidney failure, and mental retardation to their foodborne causes (Council for Agricultural Science and Technology, 1994). Even deaths from acute illnesses are difficult to identify accurately because of the gross under-reporting of foodborne disease (Council for Agricultural Science and Technology, 1994).

Identifying all Pathogens Related to Human Foodborne Disease

Given the great underreporting of foodborne disease, there is no agreed-upon list of foodborne pathogens (NRC, 1985; ICMFS, 1986; Bennett et al., 1987; Council for Agricultural Science and Technology, 1994; Petersen et al., 1994). Discussion of food safety priorities should include an evaluation of how comprehensive the list of pathogens is. New information is constantly generated by epidemiologists using new DNA fingerprinting tests that can link human illnesses with foodborne pathogens.

Monitoring and surveillance at the consumer level via outbreak investigations, tracebacks in the food chain as far as possible, and support for wider reporting of food-borne illnesses are extremely important. The underreport-ing at the present time presents a vast area for improve-ment of data. The use of self-reporting to toll-free phone lines, increased awareness on the part of the public, and other approaches could improve data in this area. The CDC has also proposed increased surveillance at sentinel sites scattered across the United States for foodborne pathogens causing diarrheal symptoms (CDC, 1994).

Measuring the Magnitude of the Foodborne Disease Problem

There are a variety of methods for estimating the distri-bution of severity outcomes for human foodborne illness and the incidence of pathogen-associated foodborne disease. The evaluation of magnitude and incidence may be qualitative (Orr and Cohen, 1991), semiquantitative (Gay and Orr, 1993), or quantitative (Kaplan, 1993). Several quantitative criteria could be used to estimate the magnitude of the foodborne disease problem: estimates of the number of acute foodborne human illness cases; number of acute human foodborne deaths or other severity factors; number and severity of chronic food-borne illnesses; quality-adjusted life-years lost because of specific foodborne diseases; damages to society because of acute and chronic foodborne illnesses (such as medical costs and loss of productivity); and society's willingness to pay for reducing foodborne disease risks, which indicates the level of concern about food safety.

The differences between two methods of setting priori-ties—counting acute illness cases versus estimated economic losses associated with salmonellosis—are illustrated in figure 6. When disease incidence is used as a measure, mild cases of human illness dominate the estimates. In contrast, when a cost of illness method is used to estimate current damages to society (medical costs and loss of productivity), deaths are the most important contributor to costs. The decisionmaker in a food firm or the Government, then, is left with two different impressions of what to target, the mild cases or the deaths from salmonellosis.

Figure 6
Foodborne salmonellosis

Number of human cases

Damages to society (dollars)
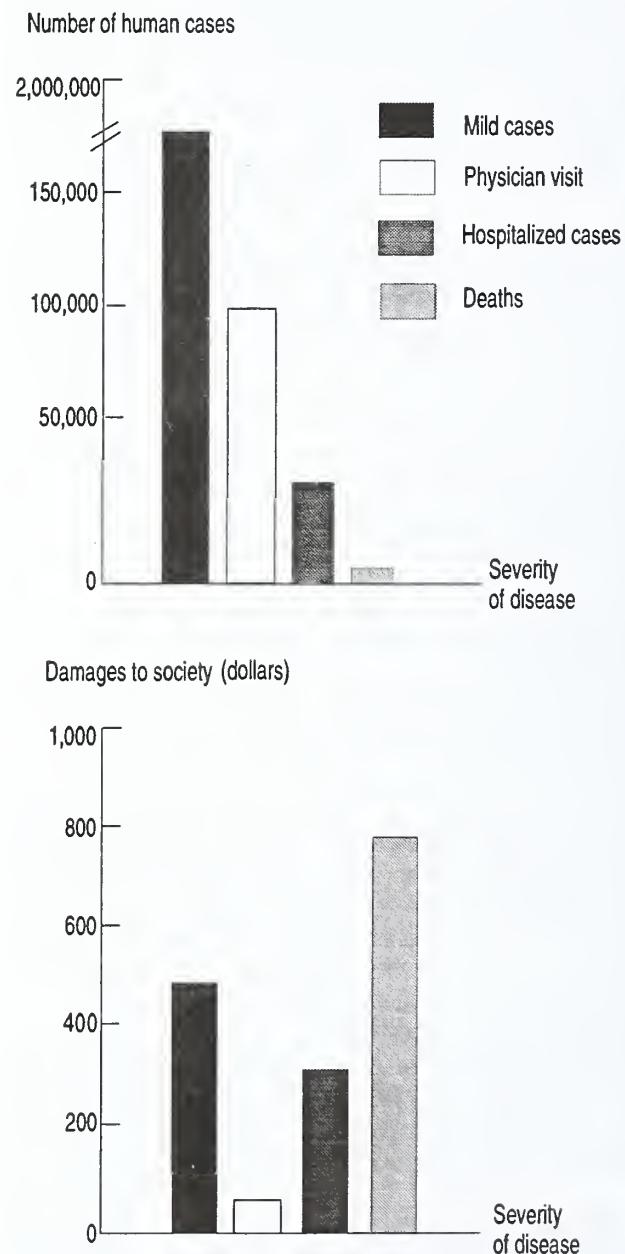
Making comparisons among several pathogens compli-cates the picture even more. Several groups, however, have attempted to set foodborne pathogen priorities.[2] In "Healthy People 2000" (USDHHS, 1991), the number of cases of acute illness plus severity were used in an ad hoc manner to identify the four most important food-borne pathogens (table 3). USDA's Pathogen Reduction Task Force identified six priority foodborne patho-gen—those in "Healthy People 2000" plus two others "identified by CDC being significant in foodborne illness of meat and poultry" (USDA, 1994, p. 2).

FSIS' Technical Assistance Group on risk assessment created an index of frequency and severity factors for both acute and chronic cases of foodborne illness (table 4). The total rank for a pathogen is the sum of the acute illness and chronic illness ranks, according to the expert judgment of the committee. They concluded that six foodborne pathogens were priority pathogens.

Preliminary work by Petersen et al. that was presented at the Society of Risk Analysis meeting in December 1994 used hazard and exposure factors to rank the severity of

[2]In 1986, the International Commission of Microbiological Specifica-tions for Food grouped microbial pathogens into categories on the basis of risk: I—Severe Hazards; II—Moderate Hazards: Potentially Extensive Spread; and III—Moderate Hazards: Limited Spread. First, this list needs to be adopted to the United States and updated to 1995. Second, placement in the "I—Severe Hazards" group implies that the hazard is more important than "II—Moderate Hazards: Potentially Extensive Spread," an assumption that bears discussion.
I—Severe Hazards: *Clostridium botulinum* types A, B, E, and F; *Shigella dysenteriae; Salmonella typhi, paratyphi* A, B; hepatitis A, E; *Brucella abortus, B. suis; Vibrio cholerae* 01; *Vibrio vulnificus.*

II—Moderate Hazards: Potentially Extensive Spread—*Listeria monocytogenes; Salmonella* spp.; *Shigella* spp.; enterovirulent *Esche-richia coli* (EEC); *Streptococcus pyogenes; Rotavirus*; Norwalk virus group; *Cryptosporidium parvum.*
III—Moderate Hazards: Limited Spread—*Bacillus cereus; Campylo-bacter jejuni; Clostridium perfringens; Staphylococcus aureus; Vibrio cholerae,* non-01; *Vibrio parahemolyticus; Yersinia enterocolitica; Giardia lamblia.*
The National Academy of Sciences has also grouped foodborne pathogens by risk groups (National Research Council, 1985).

Table 3—Group priority ratings of foodborne pathogens[1]

Pathogen	"Healthy People 2000"	Pathogen Reduction Task Force	FSIS/ APHIS TAG	Petersen[2]	Roberts
Salmonella, nontyphoid	x	x	1	2	2
Salmonella enteritidis	x	x			
Listeria monocytogenes	x	x	5	3	5
Escherichia coli O157:H7	x	x	4	1	4
Campylobacter jejuni	x	x	2	5	3
Staphylococcus aureus		x			
Clostridium perfringens		x			
Toxoplasma gondii			3	4	1

[1]X = Rated as high priority.
[2]Risk is estimated only for consumption of beef.

Table 4—FSIS/APHIS Technical Assistance Group criteria for ranking foodborne illness

Acute illness rank	Rank of pathogen incidence + Rank of pathogen average illness severity
Chronic illness rank	Rank of pathogen incidence + Rank of pathogen average illness severity
Total rank	Acute illness rank + chronic illness rank

risks associated with beef consumption for 25 pathogens and identified 5 as being most important. Roberts' cost estimates can be used to rank the damages to society from foodborne pathogens, although cost estimates do not exist for all pathogens or even all disease consequences for the pathogens examined. Still, the top three have estimated costs of $1 billion or more annually; those ranked 4 and 5 have costs exceeding $200 million annually; and three others had costs estimated at less that $1 million annually (Roberts, 1994; USDA FSIS, 1995).

Discussion

The complexities of food production, distribution, and consumption and the associated probability distributions of risk from foodborne pathogens make food safety risk assessment and management impossible to do on an ad hoc basis. There are techniques and methodologies that have been used in a wide range of other disciplines for nearly 50 years that allow us to be more structured and precise when we talk about risk and safety. They give us far more power to analyze and understand the chain of risk and safety than only referring to the extremes. This power to analyze is found in the scientific field of risk assessment.

Risk analysis in food safety is most developed in the area of chemical hazards, and least advanced in the area of microbial and other biohazards. The incorporation of replicating organisms in the context of modern, probabilistic risk analysis is just beginning with the development of "predictive microbiology" in food safety analysis. The National Academy of Sciences' "Red Book" four-step risk-assessment procedure was developed to analyze chemical hazards. It can be applied to viruses and parasites that do not replicate in food. For bacterial pathogens, it can be useful once food is on the fork. In all cases, the variability in risk that is associated with foods consumed must be acknowledged due to differences in individual susceptibility, food preferences, and so on (Buzby, 1995; Steahr, 1995; Ralston, 1995). However, the four-step risk-assessment procedure does not work well for interpreting the significance of bacterial pathogens at earlier links in the food chain.

We are proposing PSA and its close relative, FTA, as tools to systematically analyze and interpret risk data, to put data into a systems framework for improving our understanding of the relationships within and between each link of the food safety chain, to aid in identifying data priorities for foodborne pathogens, and to facilitate analysis of the marginal costs and benefits of mitigation

options. Its method of structured analysis, implicit treatment of uncertainty via quantification of model parameters in terms of probability distributions, ability to estimate the outcomes of system interventions, and inherent clarity associated with the process is making PSA the gold standard to which other methodologies are compared.

Each pathogen will have a unique PSA because of a unique mode of entry into the food chain, the likelihood of spreading within and between links in the food chain, and/or its response to different mitigation measures. However, it may be possible to develop a generic PSA to facilitate development of each pathogen-unique PSA. Significant amounts of data are needed to construct each pathogen-unique PSA or FTA, as highlighted in figure 5. Improved data are first needed to better identify the incidence and severity of acute and chronic human illnesses caused by various pathogens. Pathogen consequences then need to be measured via such methods as estimating damages to society or expert opinion on relative importance. Then data are needed on the effectiveness and the costs of mitigation options for each pathogen at all links in the food chain.

PSA and FTA can highlight high-risk pathways, identify options for reducing risk, and estimate quantitatively or qualitatively the effectiveness of options. The costs of the alternative mitigation options can be estimated and compared to the likely improvement in human health as a result of the mitigation (McDowell et al., 1995). This process generates a comprehensive and comprehensible set of decision-relevant information for managers that explicitly addresses tradeoffs in costs and benefits, as well as nonmonetary considerations. It also highlights which pieces of data are most important to collect first.

In summary, this paper has discussed the risk-assessment steps in table 5 for identifying all foodborne pathogens; identifying the acute and chronic illnesses associated with these pathogens; setting criteria for measuring their magnitude (for example, incidence of illness versus economic costs of these illnesses); and using PSA and FTA to identify high-risk food production/transportaation/slaughter/processing/retailing/consumption practices at each link in the food chain, as well as identifying where effective mitigation options might occur. McDowell et al. (1995) discuss the subsequent risk-management steps: determining acceptable risk levels for society, determining the most cost-effective mitigation strategies, identifying other considerations, and presenting food safety options to decisionmakers.

Table 5—Steps in assessing and managing foodborne pathogen risks

1. Identify all pathogens (bacteria, parasites, viruses, fungi) that can cause human foodborne disease.

2. Identify all acute and chronic human illness associated with these pathogens and estimate foodborne incidence.

3. Agree on what criteria will be used to measure the magnitude of the foodborne disease problem.

4. Identify high-risk food production/transportation/slaughter/processing/retailing/consumption practices.

5. Identify which mitigation options are most effective in reducing foodborne risks.

PSA and FTA are very useful tools at these steps

6. Determine how much foodborne disease risk is acceptable.

7. Determine the most cost-effective mitigation options to achieve the desired level of safety.

8. Identify other considerations, such as consequences to high-risk groups.

9. Present options to decisionmakers.

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Managing Risks from Foodborne Microbial Hazards

Robert McDowell
Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Stanley Kaplan
Bayesian Systems, Inc.

Alwynelle Ahl
Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Tanya Roberts
Economic Research Service, U.S. Department of Agriculture

Introduction

In addition to the empirical analysis or determination of risk, risk analysis includes managing risk or determining what level of safety is appropriate and how to achieve that through risk mitigation. Risk management in food safety includes at least three primary activities:

1. Setting priorities for mediation, e.g., which organisms take priority over others in allocating resources.

2. Determining what level of safety is appropriate—how much risk is acceptable.

3. Determining how to most efficiently achieve the desired level of safety.

As will be seen in the following sections, these three activities are interconnected and determined from a mix of empirical facts (such as cost, efficacy, and amenability to mediation) and intangibles or value-laden considerations (such as relative seriousness of specific diseases, reducing morbidity versus reducing mortality, and equity issues involving susceptible subpopulations). The following discussions of food safety decisionmaking will maintain a clear distinction between "matters of fact" and "matters of value," one of the principles of determining safety effectively in a public setting (Lowrance, 1976). As in risk assessment, the analytical methods drive the data requirements for risk management; the following sections outline some potential methodologies and their data requirements for setting safety levels and identifying efficient hazard mitigation strategies.

Determining Acceptable Risk

In a separate paper (see "Risk Assessment for Foodborne Microbial Hazards" in this proceedings), we addressed elements of risk assessment: identifying, characterizing, and quantifying hazards, which are all empirical, objective activities. However, setting standards or determining appropriate safety levels is a normative task that encompasses a number of nonmonetary or intangible considerations, as well as empirical facts produced by risk analysis.

Approaches to Setting Safety Standards

A variety of approaches to setting standards have been used in food safety; one primary method is the dose-response model for suspected carcinogens. It focuses on determining "safe" levels expressed as a function of exposure to a particular dose for a specific period of time (Hathaway, 1993). Two considerations suggest that the chemical hazard model may not be the best or even a workable a model for analyzing microbial hazards—especially when considering risks from pathogens with infective doses as low as 10 organisms. First, risk analysis in food safety is most advanced with regard to chemical hazards and least advanced with respect to microbial hazards (Hathaway, 1993), thus risk assessment for the latter lacks the detailed conceptual framework and concomitant risk assessment models associated with a more mature application. Second, the problems associated with analyzing risks from foodborne microbial hazards are very different from those encountered when analyzing risks from chemical hazards (Hathaway, 1993). Microbial agents differ from chemical hazards in several ways: they can enter the food chain in a number of locations; they can be spread by contact from one animal to another; they can be aerosolized in the slaughter and processing phases, thus potentially contaminating large amounts of product as well as exposing workers to pathogens; and they can multiply many orders of magnitude under favorable conditions (Roberts et al., 1995).

Other ways of setting safety standards have been the adoption of zero-risk standards, setting threshold levels, comparative or balancing risk standards, as low as

reasonably achievable and recommendations that "the optimal use of inspection resources should not seek to eliminate all hazards but to remove all major hazards and ensure that any residual hazards are minor in nature and exist at a prevalence that constitutes a 'negligible' risk to the consumer" (Hathaway, 1993).

In the United States, most safety standards have been set by three primary methods (Whipple, 1986):

1. Cost-benefit analysis or optimizing net gains of safety improvement by creating standards that equate marginal benefits to marginal costs.

2. Risk-level or safety-goal approaches to ensure that individual risks are acceptably low (what constitutes low depends on the circumstances).

3. Technology or engineering/process standards that specify acceptable safety as that achieved by implementing specific technological or management practices.

Considerations in Setting Safety Standards

With the exception of cost-benefit analysis, these methodologies rely on ambiguous words such as negligible, reasonable, and acceptable. Safety standards that address these ambiguous requirements are based on a number of criteria. In his review of acceptable risks, Whipple (1986) identifies five primary considerations that are involved in determining acceptable safety levels:

1. Risk (likelihood and consequences).

2. Benefits or values of products/services/activities.

3. Alternate risks (risks associated with alternatives to product or technology).

4. Risk mitigation opportunities (primarily efficacy and cost).

5. Statutory, political, and practical considerations.

In addition, the reasonableness of a safety determination may also be judged by the legitimacy of the decision process, the public's perceptions of the risks, and the perceived balance of equity (fairness) with efficiency (cost). Included in equity considerations are whether clearly identifiable subpopulations, such as infants, alcoholics, diabetics, elderly people, organ transplant recipients, and human immunodeficiency virus (HIV)-positive individuals are at higher risk. Special consideration for high-risk individuals is a complex issue. Because risks vary by pathogen, it can be difficult to

identify high-risk people. For example, children have a high risk of developing kidney failure from *Escherichia coli* O157:H7; fetuses are sensitive to *Listeria monocytogenes* and *Toxoplasma gondii*; HIV carriers are susceptible to *Toxoplasma gondii*, *Salmonella*, *Taenia solium*, and *Cryptosporidium parvum*; infants are at risk from *Salmonella* and *Campylobacter*; and the elderly are at risk from all of the above.

Another factor important in managing risk is consumers' preferences for controlling risks themselves by eating their meat cooked well-done versus their pre-ferences for the flavor and texture of rare meat. Other considerations include the "dread" associated with certain foodborne disease outcomes and the consumers' ability to perceive/understand food safety risks. Risks are some-times perceived as being absent or present, rather than on a continuum.[1]

Despite the criticism that analytical decision models discount the nonquantifiable aspects that are often so important in policy decisions (Leavitt, 1975; March, 1974), one of the primary motivations for using quantitative assessment and an analytic decision method is that such an approach permits the conceptual separation of technical factors (matters of fact) that determine risk and the political factors (matters of value) that determine safety (Whipple, 1986; Lowrance, 1976).

Establishing of any system, method, or approach for setting safety standards must take into account the many ways that safety is determined and the diverse objectives that enter into judgement of acceptability. In the end, safety is a judgmental quantity; something is safe enough if society decides it is (Lowrance, 1976).

Benefit-Cost Analysis in Setting Safety Levels

While multiattribute decision models have been developed and adapted to a variety of public safety problems (Krzysztofowicz and Duckstein, 1980; Chankong and Haimes, 1983), they have not been applied, to our knowledge, in food-safety risk management. However, the benefit-cost method—a special case of multiattribute decisionmaking that is based on optimizing for attributes, benefits and costs—is a relatively straightforward application of economic theory to setting food safety levels. Benefit-cost analysis has been applied to evaluating the economic feasibility of irradiation to control microbial

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[1]For example, our society often communicates in polarized terms: yes/no, rich/poor, safe/unsafe, risky/risk-free—all of which represent extremes. Yet nothing is totally free of risk or uncertainty in outcome.

pathogens in pork, chicken, and beef (Roberts, 1985). The benefit-cost paradigm has also been used to examine the economics of enforcing food safety standards (van Ravenswaay and Bylenga, 1991). A listing of cost-benefit analyses pertaining to managing microbial hazards is contained in a broader review of the economic aspects of foodborne disease in the United Kingdom (Sockett, 1993).

In a broad sense, economics can perform three primary functions—normative, descriptive, and prescriptive—in analyzing and managing risk in food safety:

1. Normative—establishing the level of safety that maximizes net benefits (total benefits from risk mitigation minus costs of achieving those benefits) to society.

2. Descriptive—quantifying the cost and performance of food safety systems (by economic analysis that is complimented by systems analysis and reliability modeling);

3. Prescriptive—specifying the most economically efficient way to obtain a given level of safety, or to maximize safety for a specified cost.

Normative Economics: Setting Appropriate Levels of Food Safety

For producing social welfare in the form of food safety or producing profits for an individual firm, economic theory provides a guide for maximizing the net benefits to society or the firm's owners. It helps determine the optimal level of production for a profit-seeking firm, where the difference between total costs and total revenues is maximized. Algebraically, given mathematical functions describing total revenue and total costs as functions of output, profit is maximized where the slopes (first derivative of each function) are equal (Doll et al., 1968).

As an economic activity, "producing" food safety differs from typical market-oriented economic activities—and resembles pollution control activities—in that its output is reduced frequency and/or severity of adverse health/environmental effects (e.g., reduced foodborne disease and death), rather than increased output of some commodity or service. The normative guide for society's appropriate level of food safety production is identical to that for the profit-seeking firm: maximize net benefits. In the case of food safety, social welfare is maximized by adopting food safety measures in such a way that maximizes the difference between total benefits (reduction in foodborne disease) and total costs of obtaining those benefits

(Roberts, 1986). Figure 1 illustrates the welfare-maximizing level of food safety.

Figure 1
Total benefit and total cost functions by level of inspection intensity and the resulting hazard to human health
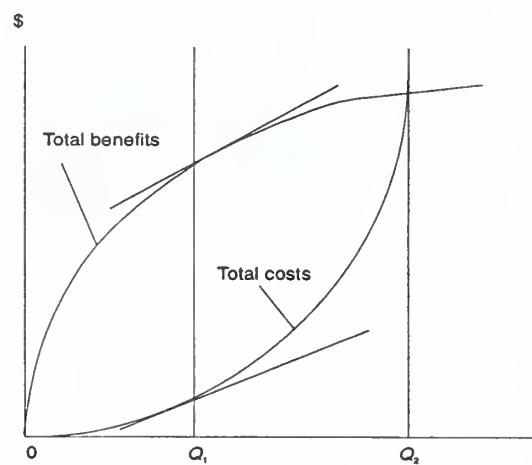
A central problem to the normative approach is valuing benefits. Despite advances in economic theory of valuing health benefits, substantial value issues are involved in this problem that make precise and generally agreed-upon monetary valuation of all benefits from food safety difficult. Despite the lack of a single definitive monetary standard for loss of life or injury, summaries of research on the value of reducing risk of death or injury reveal results that are remarkably close, even when derived from very different methodologies and data resources. In a review of 21 studies (Fisher et al., 1989), the value of a statistical life ranged from $1.6 to $8 million in 1986 dollars. A subsequent and more detailed review of 41 prior studies involving a number of different methodologies, data bases, and approaches (Viscusi, 1993) revealed that nearly all resulted in values between $3 and $7 million per life. Converting all effects of foodborne illness and death permits economic theory to be applied to the problem of maximizing the net benefits to food safety.

Analysis for Selecting Cost-Effective Methods of Reducing Foodborne Hazards

Descriptive economics and systems analysis are simply tools to quantify the costs and performance or output of hazard-mitigation practices in terms that produce

decision-relevant information. Regardless of how precisely the benefits of hazard mitigation are measured, an appropriate metric that relates management practices to reduced frequency of foodborne illness and death is needed to evaluate management options and to determine economically efficient stratagems or sets of mitigation practices.

Despite the apparent dissimilarity of food safety to mitigating natural and technological hazards such as tornados, floods, and dam failures, the quantitative techniques of risk-based decisionmaking that have been applied extensively to the latter—public investment in safety from environmental hazards (Haimes, 1981)—can be applied to food safety. The organizing principles, guides to optimization, and opportunities for enlightened risk management are generally the same, regardless of the specific hazards involved.

A framework for rationally evaluating alternatives and for decisionmaking regarding appropriate input use and combinations of technologies can be developed by using a combination of techniques from systems modeling, reliability analysis, decision theory, and economics. This phase—prescriptive economics—provides the tools for decisionmaking relating to how best to achieve safety standards that are predicated on both monetary and nonmonetary considerations.

These methods may be particularly useful in addressing one of the most vexing problems in the area of food safety, selecting appropriate combinations of hazard-mitigation techniques. The farm-to-table chain presents numerous opportunities for hazard mitigation. As discussed in "Risk Assessment for Foodborne Microbial Hazards" in these proceedings, probabilistic scenario analysis and fault tree analysis are tools for systematically identifying high-risk pathways and/or practices/behaviors by all participants in the food chain. These high-risk pathways then become candidates for risk-mitigation strategies.

The food safety manager is faced with the problem of assembling a "portfolio" of mitigation techniques to obtain some desired level of safety (or maximizing safety for a given cost). The primary obstacle to rational decisionmaking in this arena is the exponential explosion of possibilities: n hazard reduction techniques that can be used alone or any combination with each other generate $2^n - 1$ unique combinations (or 2^n if no hazard mitigation is one alternative). Given 10 techniques, 1,023 combinations or options exist; 30 techniques[2] yield slightly in

excess of 1 billion options (1,073,741,823 options, to be exact). The likelihood that a decisionmaker can, without analytical assistance, specify risk-efficient combinations of these 1 billion-plus mitigation techniques is remote, thus creating the need for an analytical framework to define our preferences and to identify efficiently combinations of techniques that satisfy these preferences.

The Pareto criterion[3] provides a simple and elegant choice or preference model. Originally used to specify choices among income distributions (Stokey and Zeckhauser, 1978), it can be generalized to decisionmaking that involves tradeoffs between multiple objectives:

> Solution A is preferred to solution B if it satisfies one objective to a larger degree than does solution B, and it satisfies the other objective(s) at least as well as solution B.

If, from a given solution K, we are unable to find a solution that is preferable by the Pareto criterion, solution K is defined as *Pareto optimal.* For the purposes of this paper, Pareto optimal solutions will be referred to simply as optimal solutions.

In the food safety setting, two competing objectives are cost and safety, which we wish to minimize and maximize respectively. Figure 2 illustrates the Pareto criterion and the concept of optimality in the context of hazard mitigation techniques for a food safety system. Given that safety *increases* as Y (frequency of adverse event) *decreases*, option 3 is preferred to options 4 and 5 by the Pareto criterion; it increases safety while decreasing costs. Option 3 is also preferred to option 2; it increases safety without changing cost. Options 2, 4, and 5 cannot

Figure 2
Cost and performance characteristics of five hazard mediation techniques

Event frequency: $Q(0) = 1$

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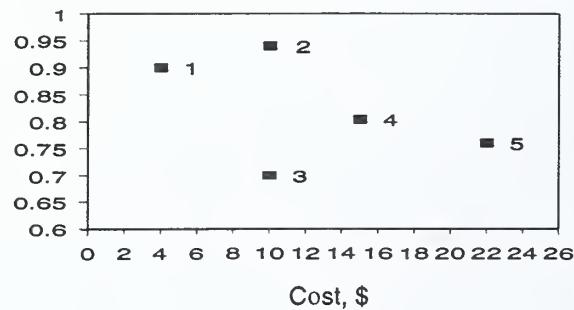
[2]From a systems standpoint, a specific hazard mitigation technique that can be used in m places in the farm-to-table continuum is equivalent to m distinct techniques.

[3]Named for Vilfredo Pareto, Italian economist and sociologist, 1848–1923.

be distinguished from each other by the Pareto criterion. Considering the entire set of five options, only 1 and 3 are Pareto optimal; that is, no option superior to either can be found using the Pareto criterion. Note that 1 and 3 lie on an envelope that bounds the options; this is called the *Pareto optimal frontier* or efficiency frontier. In the following section, the application of the Pareto criterion is demonstrated in a hypothetical food safety decision problem.

Identifying Efficient Sets of Risk Mediation Techniques: A Hypothetical Example

Consider a food production/processing system in which a raw product enters, is subject to five possible risk-mitigation practices that are arranged serially, and leaves the process. Figure 3 contains a scenario tree illustrating such a system. Furthermore, each technique can be applied alone, applied serially with any combination of the other techniques, or not at all. In the absence of mediation, Q_0 adverse events occur per arbitrary time units or number of demands on the system.

Table 1—Cost and efficacy of five independent risk-mitigation techniques

Technique	Cost	k-value[1]
	Dollars	
1	4	0.90
2	10	0.94
3	10	0.70
4	15	0.80
5	22	0.76

[1]The k-value, a measure of efficacy, is equal to the frequency of system (when a given technique is used) divided by system failure rate when no mitigation practices are used. Thus, when technique 1 is used, the system failure rate is 90 percent of that when no mitigation practice is used (or failure rate declines by 10 percent).

Figure 3

Hypothetical scenario tree for potential risk-management options in food processing

Start   Potential Risk-Mitigation Points   Finish
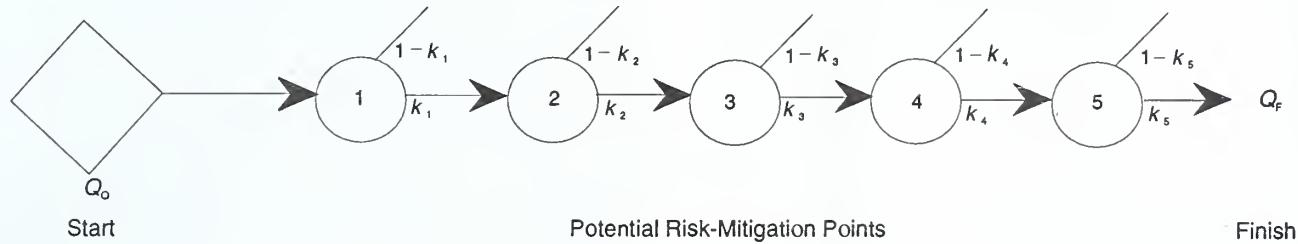
Each technique has two primary characteristics:

1.   Cost, where C_i is the cost of the ith technique, and

2.   Effectiveness, quantified as k, where

$$k = Q_i / Q_0$$

and Q_i is the frequency of adverse events when the ith mediation technique is applied.

(Hence $k = pr$ (failure) of ith technique on an individual trial. Note that lower k values connote higher safety levels.)

The cost and efficacy of five hypothetical hazard mitigation techniques are summarized in table 1 and displayed graphically in figure 2. For the purpose of

prescriptive analysis, these two characteristics—cost and performance or hazard reduction—summarize the important descriptive information pertaining to any technique. Uncertainty and/or variability in cost or effectiveness are not considered in this analysis. Given that these techniques are applied serially, the resulting frequency of adverse events when an arbitrary failure set, S_a, is applied is the product of the individual k values (Hillier and Liebermann, 1974):

$$Q_a = k_{a1} \times k_{a2} \times ... \times k_{ai}.$$

The cost of set S_a is sum of the individual costs, ΣC_{ai}.

Five independent mitigation practices yield $2^5 - 1$ or 31 possible combinations. The cost and system reliability for all stratagems arising from these five practices were computed (table 2) as described previously. Plotting the vector of cost and reliability points for all possible

Table 2—Cost and performance of risk management stratagems formed by combinations of five independent risk-mitigation techniques

Options	Cost	k-value[1]
	Dollars	
1	4	0.900
2	10	0.940
3	10	0.700
4	15	0.800
5	22	0.760
1,2	14	0.846
1,3	14	0.630
1,4	19	0.720
1,5	26	0.684
2,3	20	0.658
2,4	25	0.752
2,5	32	0.714
3,4	25	0.560
3,5	32	0.532
4,5	37	0.608
1,2,3	24	0.592
1,2,4	29	0.677
1,2,5	36	0.643
1,3,4	29	0.504
1,3,5	36	0.479
1,4,5	41	0.547
2,3,4	35	0.526
2,3,5	42	0.500
2,4,5	42	0.500
3,4,5	47	0.426
1,2,3,4	39	0.474
1,2,3,5	46	0.450
2,3,4,5	57	0.400
1,3,4,5	51	0.383
1,2,4,5	51	0.514
1,2,3,4,5	61	0.360

[1]Efficacy as measured by system reliability; k-values are the system failure rate as a proportion of failure rate when no risk mitigation is used. The k-values of combinations are the product of the k-values for component techniques.

stratagems (figure 4) begins the process of defining and identifying efficient sets of mediation practices. The set of optimal stratagems—those preferred to all others—are shown as filled squares in figure 4. All nonoptimal stratagems are dominated, either by cost, reliability or both, by one or more stratagems located on the envelope or lower boundary of the points that identify stratagems.[4] The dominated solutions are discarded as potential solutions; thus, the obvious benefit of identifying undominated solutions lies in reducing the complexity

[4]This is outcome and cost dominance as opposed to stochastic or probabilistic dominance (Holloway, 1979).

Figure 4
Cost and performance of 31 combinations of 5 risk-mitigation techniques

Relative frequency of system failure

■ Optimal stratagems
◆ Nonoptimal stratagems
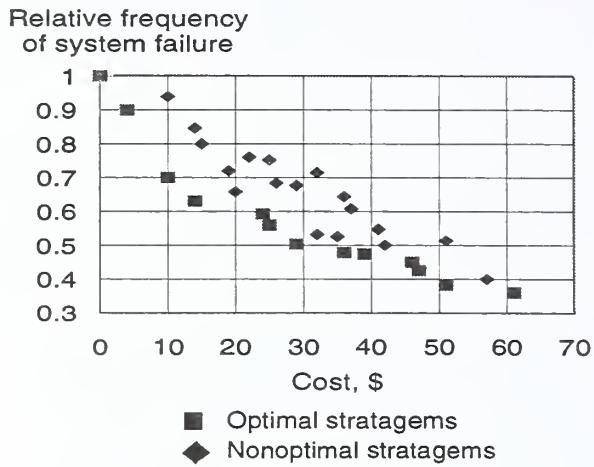
of the decision problem. In this example, the decision problem has been reduced from 31 options to 12, or by about two-thirds. In a more realistic problem, for example one with 30 techniques and thus about 1 billion options, assuming 1000 optimal stratagems, the complexity is reduced by 99.9999 percent—not a trivial reduction.

A subset of size n (recall that n is the number of independent risk-mitigation techniques available) of the optimal stratagems can be identified directly by n iterative calculations, thus avoiding the burden of computing the cost and effectiveness of all $2^n - 1$ options, and plotting and identifying the efficient stratagems by inspection or algorithm (McDowell and Kaplan, 1994). This subset of the optimal solutions for the hypothetical systems is shown in figure 5.

Figure 5
Subset of Pareto optimal solutions identified by analytical shortcut method[1]

Relative frequency of system failure

Optimal solutions
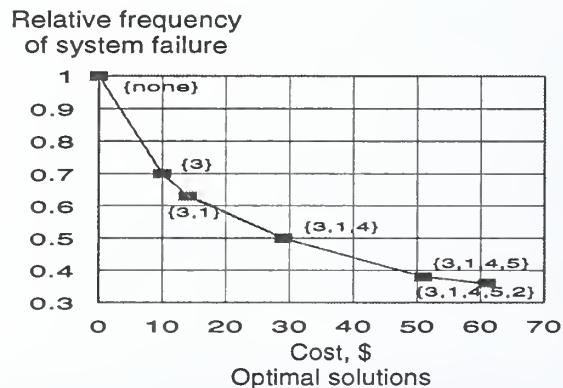
[1]Numbers in brackets indicate the combination of techniques that defines the particular point.

This method has several valuable attributes for decision-making in food safety:

1. It separates the normative phase (how much food safety) from the empirical or objective phase (how best to obtain a given level of food safety).

2. It greatly simplifies the decision problem by identifying the small group of preferred alternatives without computing the costs and performance of all possible options (e.g., more than 95 percent reduction in decision problem complexity).

3. It explicitly quantifies the monetary and safety tradeoffs of choosing one alternative over another.

4. It allows explicit accounting of the cost (either in dollars or reduced safety) of making suboptimal decisions to satisfy other nonmonetary objectives.

5. The resulting decision is based on a process in which all pertinent assumptions are clearly specified and documented.

6. The results, based on rational rather than haphazard determination of choices, achieve the most efficient use of private and public resources devoted to food safety.

7. The decision criterion for selecting optimal stratagems is very simple and self-evident from a simple graphic display; no mathematics beyond arithmetic are required to perform the analysis.

The alternative to analysis is to address the problem in descriptive terms and develop a solution that seems to meet our requirements. Given a decision problem with 1 billion options, this sounds like a reasonable approach. However, the solution we obtain will undoubtedly be risk-inefficient; that is, there exists another solution with identical cost that generates more safety, or for the level of safety obtained, there exists another solution that yields the same safety at lower cost.

Given the option of specifying, costing, and estimating the performance of $2^n - 1$ mitigation stratagems and then identifying those optimal solutions, the inefficiency associated with a suboptimal choice obtained by some ad hoc procedure is probably less than the cost of determining the group of economically optimal solutions analytically. However, a substantial subset of these optimal solutions can be obtained at a small fraction of the analytical cost of analyzing all possible options (McDowell and Kaplan, 1994). Using this more direct analytical approach allows managers to economically select optimal strategies, avoiding the inefficiencies inherent in solutions devised by naive selection methods.

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The Economics of Regulation and Information Related to Foodborne Microbial Pathogens

Helen Jensen
Iowa State University

Laurian Unnevehr
Economic Research Service, U.S. Department of Agriculture

Introduction

Previous papers in this conference have examined the data available to track foodborne pathogens from their sources to resulting illness for consumers. In this session, Roberts, Ahl, and McDowell have shown us how such data might ideally be put to use in risk assessment. Beyond risk assessment, however, is the need for data to inform public policy decisions about managing the risks from foodborne pathogens and options for controlling the level of safety in the U.S. food supply. Good public policy decisions and consideration of regulatory options involve choices. Alternatives are weighed based on their costs and benefits, which in turn requires knowledge about producer and consumer behavior and their responses to incentives. While many alternatives may have positive benefits, it is important to identify those with the highest benefits relative to costs. Because economic costs and benefits matter in public policy, we focus on data needs that will support choosing cost-effective public policies and generate incentives that are appropriate to achieving improved food safety.

In our paper, we examine how data can be used to evaluate policy options for managing the risks from foodborne microbial pathogens. We begin by reviewing the current policy structure for managing food safety risks, then we discuss the nature of the failure in markets for food safety and the range of options for intervention. Next we discuss how evaluation might proceed for either a standards-based approach that is focused on the Hazard Analysis Critical Control Point (HACCP) system, or for incentive-based approaches that are focused on providing information. Finally, we provide an overview of the data that are needed for an economic cost-benefit analysis of policy options.

Policy Background

The current system for assuring a safe supply of meat in the United States has evolved over the years, largely in response to changes in the production, processing, and distribution of meat products. Federal meat inspection

legislation for ensuring the wholesomeness of American beef and meat dates back to 1890 (USDA FSIS, 1995). The Federal Meat Inspection Act of 1906 established today's standards for slaughter and processing of meats, including postmortem inspection of carcasses. Poultry products were added under the Poultry Products Inspection Act of 1957. Both antemortem and postmortem inspection of animals and sanitary standards for slaughter and processing facilities come under the legislation.

Today, two different Federal agencies share primary responsibility for ensuring the safety and quality of meat and poultry products: the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), through inspection of meat, poultry, and eggs; and the Food and Drug Administration (FDA), which is responsible for ensuring the safety of domestic and imported food products by establishing standards of identity and quality, and regulating food processing and food establishments (except for meat, poultry, and some egg products).[1] Seafood also comes under FDA jurisdiction.

In addition to establishing standards of identity and quality, FDA's primary responsibility is to protect human health from food hazards after food enters the market. FDA has limited jurisdiction over meat and poultry production processes, only acting when there are actual or potential contamination or unsanitary conditions in its distribution.

In contrast to FDA, FSIS focuses on inspection of the processing and safety of food before it enters the final marketing and distribution channels. FSIS administers meat and poultry inspection in slaughtering and processing plants. FSIS inspection relies primarily on the inspector's sight, smell, and touch to detect abnormalities in

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[1] Food safety activities at USDA, including on-farm programs and egg inspection, have recently been consolidated under FSIS. In addition to FDA and FSIS, other agencies play a peripheral role in meat product food safety through their authority over particular issues. For example, the Environmental Protection Agency sets pesticide residue tolerances for all foods, including meats. In addition to Federal activities, State and local authorities have jurisdiction over food retail establishments.

animals or carcasses, with on-the-spot corrective action. Recently, FSIS has taken steps to develop an inspection system that is based on more formalized assessment of the risks that are present in slaughter and processing plants (USDA FSIS, 1995).

However, the food safety problems of greatest concern today can neither be consistently identified through the current FSIS inspection programs nor be controlled through the FDA's standards and procedures (USDA FSIS, 1993). The most serious foodborne threats to public health from meat, poultry, and seafood products are from microorganisms that are hard to detect and prevent with current inspection and control procedures. Producers, processors, government, and consumers all play a role in controlling microbial contamination.

The complex nature of foodborne microbial hazards means that there is no one approach that will assure complete safety from them. The analysis and assessment of risks involved in meat and poultry production, processing and distribution are essential to the development of public strategies for managing food safety risks, for appropriate regulatory response, and for creating incentives for producers and consumers to achieve improved food safety levels. The rest of this paper considers the economic aspects of the issue, and how economic analysis can help to choose among management strategies.

How Economists Define the Food Safety Problem

Safety is an attribute of food products associated with reduced risk or chance of foodborne illness. If consumers can ascertain the level of safety or risk associated with a food prior to its purchase and understand the true risks to health, then they could choose among products to obtain the preferred level of food safety. In doing so, consumers could express their willingness to pay for varying levels of safety. A market for safety attributes would exist, with the cost of safety (including the personal "costs" of taking precautions) balanced against its value to consumers. However, safety usually is not ascertainable directly. Consumers do not always have complete information about the safety of food when they buy it. Furthermore, if they become ill from foodborne pathogens, they may have difficulty recognizing the source. Producers or processors also do not always have information about the safety of their products, and it may be costly or impossible for them to respond to consumer demand for improved safety. This lack of information creates a "market failure." Producers have little incentive to provide greater levels of food safety, since consumers will not pay for an attribute that they cannot verify.

Another aspect of this market failure is that the transaction costs of reaching agreement on the level of safety and the price premium are high. Although the current legislative and legal systems determine who is responsible or "at fault" for failure to assure safe food, the costs of actually deciding who is at fault are often very high. Given the fact that food handling from "farm to table" contributes to the final product, there is a relatively high degree of integration required to protect the food supply. Hence, it is difficult to identify who is at fault when a failure occurs. High transaction costs associated with negotiating agreements and the difficulty of assigning liability mean that private markets may fail to achieve the preferred level of food safety.
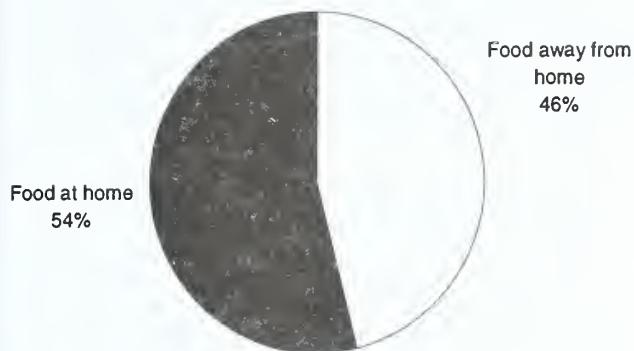
This market failure—the lack of information about safety and the high costs of achieving agreements privately—creates a public health problem. This problem is the fundamental justification for public intervention to improve food safety. Although Federal interventions in this area date from 1890, the Government's role has been the subject of renewed attention in recent years. Several structural changes may account for the growing attention to food safety issues.

More people are highly susceptible to microbial foodborne illness than before as the population ages, as medical technology keeps ill people alive longer, and as chronic illnesses that suppress people's immune systems (such as AIDS, diabetes, and cancer) spread. A recent Council for Agricultural Science and Technology report estimates more than 30 million individuals are at especially high risk today.
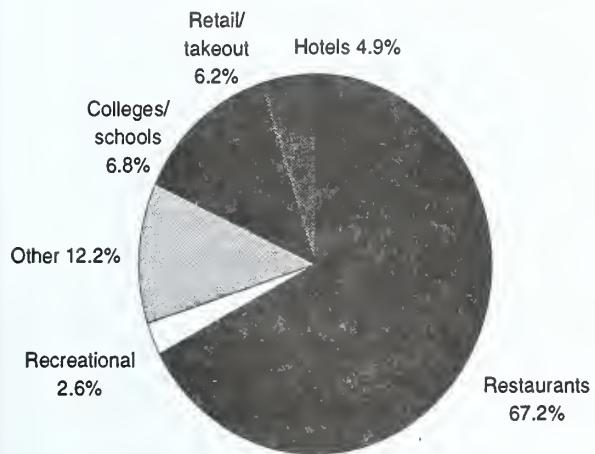
Another structural change is the growing popularity of convenience foods and food away from home. The proportion of food expenditures away from home has increased from 34 percent in 1970 to 46 percent in 1993 (USDA ERS, 1994). The food-away-from-home sector includes a wide variety of outlets in addition to restaurants (see figure 1), such as food prepared in grocery stores; food served in institutions like day care centers, college dormitories, or nursing homes; and food served at recreational establishments. The increased proportion of food consumption in the away-from-home sector reduces consumers' control over food preparation and may alter the nature of foodborne risks.

The value consumers place on food safety depends on their information about foodborne risks and their own susceptibility and ability to take precautions. News stories on recent outbreaks have heightened consumer awareness and have increased information about the nature of foodborne pathogen risks in the food supply. Thus, consumers may now place a higher value on reducing risks from microbial pathogens, even though such risks

Figure 1
Food expenditures, 1993

Food away from
home
46%

Food at home
54%

Food away from home by type of institution

Retail/
takeout
6.2%

Hotels 4.9%

Colleges/
schools
6.8%

Other 12.2%

Recreational
2.6%

Restaurants
67.2%

are small. These structural changes, the increased popula-
tion at risk, the changing structure of food markets, and
growing consumer awareness lead to greater demand for
food safety.

In addition to changes in demand, the improved ability to
supply food safety through scientific advances is an
impetus for increased attention to the regulation of food
production and distribution. New pathogen tests and
improved epidemiological methods link human diseases

to their foodborne sources. Continued development of
inexpensive, rapid tests will detect contaminants in foods
and permit statistically based testing. The adaptation of
HACCP systems to slaughter and processing for raw
meat and poultry is another technological innovation that
could lower the cost of providing a safer food supply.
These advances create new opportunities for controlling
foodborne pathogens. In other words, the cost of supply-
ing food safety is lower.

Taken together, these changes in demand and supply
suggest that a higher level of food safety should be
observed, if interventions can be designed that allow
these changes to be effective in the marketplace. Market
interventions can take many forms, but all of them seek
to address the fundamental information problem and the
need for appropriate incentives for producers and con-
sumers. We categorize market interventions into five
types (adapted from Litan and Nordhaus, 1983, p. 38),
distinguished by whether they are based on command and
control or incentives (table 1).

**Table 1—Possible interventions to correct
market failure due to insufficient
information**

Type of intervention	Examples
Command-and-control type:	
Process standards	Specifying how prod-ucts are produced
Outcome standards	Testing and inspection to ensure that products meet a particular safety standard
Mandatory disclosure	Requiring producers to reveal level of safety
Incentive-based type:	
Providing information to the public	Informing consumers about how to avoid risk; subsidizing food safety research to improve information technologies
Private bargaining	Providing voluntary certification of safety for certain producers, with possible public verification

Command and control approaches include setting standards for product content (outcome) or for processing techniques. Product control is achieved by setting standards for any product that enters the market or at various stages of the marketing channel. Visual inspection of products and setting appropriate microbiological limits at different points in production and distribution are methods of guaranteeing an end product of a specified quality. Such standards require the product's quality to be monitored (usually based on sampling and testing). In contrast, production or processing standards achieve an improved final product by directly specifying the processes or procedures to be followed in production. Examples include requiring specific product washing solutions or chill temperatures.

Mandatory disclosure of information is a command intervention that takes a different approach. For example, labeling is required for certain nutritional attributes of packaged foods, such as fat content, in order to give consumers information about product qualities that would be very costly to observe. However, it may be difficult to enforce disclosure of information about microbial pathogens, since producers do not always know the level of safety being produced or contained in the product at sale. Producers could be required to provide information on the production processes, such as irradiation, that they use.

Incentive-based approaches allow market participants to choose the use of inputs, technologies (in the case of producers), or among products or home production technologies (in the case of consumers). One way to facilitate such choices is by giving the public information. Additional product information allows consumers to more effectively weigh their willingness to pay for safer food against higher prices or to alter their own food handling instead of paying those costs. Labeling meat and poultry products with safe handling instructions is a way to give consumers information about how to reduce risks. Another example of information for the public is instruction about safe food handling for employees in food service establishments. Government can also affect the information available to industry or consumers by subsidizing food safety research that will reduce the cost of obtaining information. Incentive-based approaches are designed to induce either producers or consumers to identify and practice cost-effective methods that achieve desired (higher) levels of food safety.

Another way to motivate improved food safety is to foster opportunities for private bargaining in order to establish a market for reduced risk. This can be an effective strategy, especially where the number of "players" is relatively small or can be easily identified.

One example is in organic or "natural foods" markets, where private organizations certify organic produce or certain production methods and a market for their products has developed. Another example is where food processors privately negotiate that certain standards of production (or nonuse of certain inputs) be met by farm-level producers. Finally, markets for products that meet higher standards of safety may develop to meet the needs of self-identified high-risk populations, such as nursing home residents or the immune-suppressed population.

Evaluating a Standards-Based Approach: HACCP

The National Research Council (1985) has suggested HACCP as a standard for achieving greater safety in meat and poultry production. HACCP is already widely recognized in the food industry as an effective approach to establishing good production, sanitation, and manufacturing practices that produce safe foods that are likely to withstand some variation in food handling and storage. This strategy for controlling food processing relies on identification and control points in the production process where problems can occur.

HACCP is designed to be a preventive system that focuses inspection and resources on areas critical to achieving product safety. Prevention is seen as more cost-effective than testing a product, and then destroying or reworking it. The system can be applied to control any stage in the food system, and involves sufficient traceability and feedback in the process to direct corrective activities.

There are seven principles involved in developing and operating a HACCP program (National Advisory Committee on Microbiological Criteria for Foods, 1992):

1. Assess the hazard, list the steps in the process where significant hazard can occur, and describe the prevention measures.

2. Determine critical control points (CCP's) in the process.

3. Establish critical limits for each CCP.

4. Establish procedures to monitor each CCP.

5. Establish corrective actions to be taken when monitoring indicates a deviation from the CCP limits.

6. Establish recordkeeping for the HACCP system.

7. Establish procedures to verify that the HACCP system is working.

The HACCP system has proved to be a very effective method to focus inspection and attention on CCP's, and improve the scientific basis for safety and control processes. A CCP is "any point in the chain of food production from raw materials to finished product where the loss of control could result in unacceptable food safety risk" (Pierson and Corlett, 1992, p. 3).

The concept of CCP is key to the control system and very demanding in terms of required resources and information. Monitoring of CCP's is done best by using indicators or characteristics that are easily measurable. This focus on measurable indicators can provide a more cost-effective approach to control than product sampling and testing, which is inherently expensive and often time-consuming.

HACCP was originally developed as a management tool by the private sector, and has only recently been proposed as a regulatory tool. It has been widely applied in food processing where product liability may create a greater need for industry to control processes, than in production of unprocessed products. A recent study by Karr showed that only 10 percent of meat and poultry plants in the Northeast currently use HACCP. Adoption of HACCP requires a firm to commit resources to achieving product quality. Over 60 percent of the companies in Karr's survey indicated they lacked adequate staff to implement HACCP.

Clearly there are costs to the firm for implementing a HACCP system. Without public intervention (regulation), firms will adopt HACCP as a means of ensuring a certain safety content in their products if there is some return in the marketplace for their efforts. The standards may be adopted as part of "good management practice," or to achieve a product standard that can be identified in the market and for which consumers will pay a higher price to compensate for the additional processing costs. If Karr's adoption rate is representative, then these incentives do not seem to exist currently for most firms in meat and poultry slaughter and processing.

In adapting HACCP as a regulatory tool to correct the failure in the market for food safety, it is important to recognize that there are limits to its use. HACCP is not designed to replace management decisionmaking relative to product design, choice of inputs, or product marketing. That is, weighing potential benefits from product design and qualities against costs, as well as weighing the value of improved safety versus the costs of achieving it are aspects of managerial decisions not addressed through

HACCP processes. HACCP supports good production practices, but management (or the regulatory agency) has discretion to determine what the final product standard will be. To a large extent, these issues enter into the firm's deliberations in determining CCP's and tolerance limits at CCP's.

The explicit or implicit choice of a safety standard to be achieved through the use of HACCP has important implications for its use as a regulatory tool. Although HACCP is a process approach, in practice it may or may not be a process standard. The implementation of HACCP requires the choice of an outcome standard that the CCP's are selected to achieve.

Setting up a HACCP system involves verification (product testing) to ensure that the CCP's are working. Thus, requiring firms to adopt HACCP also implies requiring a particular standard for food safety, and the selection of the standard will have important implications for evaluating policy.

The dual nature of HACCP as both a process and a product standard is widely misunderstood. It is important because economists argue that process standards are inefficient; they specify *how* firms should achieve goals rather than specifying the product standard and allowing firms to choose the least expensive process for achieving it. From this perspective, setting product standards and allowing choice and, over time, innovation, to meet them should allow greater efficiency in meeting a particular public health goal.

However, food safety regulation is not as simple as this economic truism suggests. First, food safety outcomes are expensive to test and monitor. As mentioned previously, HACCP provides an efficient control approach because it relies on prevention and identification of measurable CCP's rather than ex post testing. Second, process standards can be rigid or very flexible in practice. HACCP is a general conceptual approach that can be adapted in many different ways to processes in individual plants and at all stages of production, processing, and distribution. Thus, its flexibility allows firms some choice in meeting the regulated standard. Third, inspection and verification by the regulatory agency can be more efficient when it is focused on prevention. Checking CCP's and verifying a HACCP program that is in place may be a more efficient way of regulatory monitoring than testing product. Thus, HACCP can have some attractive features as an efficient regulatory tool, in spite of its appearance as a process standard.

How could HACCP be evaluated as a potential policy option? The costs and benefits of any particular HACCP

regulation will depend on the accompanying implicit standard for safety improvement. The benefits would flow from that standard and the corresponding fewer cases of foodborne illness. The costs of these avoided illnesses would give a lower bound estimate of the benefits of a HACCP regulation. The costs of the regulation would be the firms' costs to set up and maintain a HACCP system. It may be important to recognize differences among firms in the costs of implementing HACCP. The challenging part of evaluating HACCP is likely to be directly linking its adoption to specific reductions in pathogens and in foodborne illnesses.

In the past, industry has applied HACCP to control hazards where a zero-risk standard is appropriate (e.g., broken glass in canned food). For microbial pathogens, particularly in unprocessed products, a zero-risk standard may or may not be appropriate. Establishing the critical limits that must be met at each CCP for microbial contamination is likely to involve many tradeoffs. Application of HACCP to these kinds of hazards will require marginal cost-benefit analyses, where the value of reducing risk to very low levels is weighed against the additional costs.

Evaluating Incentive-Based Approaches to Regulation

Consumers carry out food handling and storage. Well-informed consumers fully understand the characteristics, including the risks, of products they buy and consume, and are well-informed about (and adequately able to achieve) cooking and food handling methods that will ensure the food's safety. Thus, an alternative to regulating food safety is to shift some of the burden of choosing and maintaining product standards to consumers through practices such as food labeling. With labeling, consumers are informed about the product's characteristics but they also assume some responsibility for ensuring its safety.

Providing information is an incentive-based approach because it allows individual actors in the market to exercise choice. This has the advantage of leading to more efficient market outcomes. If a small but significant number of consumers desires greater safety, then providing information can allow that group to express their preferences through personal behavior or willingness to pay. If some firms can produce a safer product at a lower cost, then public or privately sponsored certification can allow those firms to exploit a market niche for safety, while other firms can produce at lower cost for the rest of the market. When such a market niche exists, it provides incentives over time for the development of less expensive production methods to ensure safety. It can

also allow increased demand for safer products to be reflected in higher price premiums.

Providing information suffers from some general drawbacks that are related to consumers' ability to use it. The challenge in designing this kind of intervention is to structure the information so that it allows consumers to make better decisions (Magat and Viscusi, 1992). Consumers have limited time and ability to process information, particularly with respect to small risks. They can become overloaded with information, and the impact of this regulatory tool can easily be diluted by overuse.

In addition, consumers may be prevented from exercising their choice due to the structure of the market. An increasing proportion of food is consumed away from home. Consumers in nursing homes or day care centers have little choice or control over food safety, yet they are among those who are most vulnerable to foodborne disease.

The design of information interventions can be complex. First, a risk assessment is needed to identify where behavior can be modified to reduce risk. For example, in designing information about safe handling, first it would be useful to know the incidence of pathogens in products entering the home, the incidence of foodborne illness arising from food preparation in the home, and the current use of safe handling practices by consumers. If most foodborne illness arises in the away-from-home or prepared foods subsector, then safe handling labels will have little impact. Alternatively, if most consumers already follow safe handling practices, then identifying those who do not would be a way to target educational efforts. Answers to these kinds of questions can help to assess whether or not safe handling labels contribute to better consumer decisionmaking.

The second step would be to evaluate the costs and benefits of the information intervention. Magat and Viscusi argue that interventions to provide safe handling instructions to consumers should be evaluated with respect to whether better decisions are made, which is inherently difficult to measure. If decisions are improved, then how much will risks be reduced? Only with answers to these questions can the benefits of labeling be evaluated.

Another information approach would be voluntary certification of higher levels of safety for some products. This approach allows a market to develop for higher safety, with the equilibrium premium for safety determined by the value of safety to consumers and the costs to firms of improving safety. The higher level of safety may be of particular interest to certain high-risk groups.

In this case, the public role is to certify that products meet a particular safety standard or that the production process that is advertised as leading to a safer product does in fact produce one (e.g., egg pasteurization). Choosing the safety standard that improves welfare is the challenge. Safety is a continuous attribute, but certification generally distinguishes only between high and low quality. The high-quality product needs to have a safety difference great enough to elicit a price premium. However, if the safety level is too high, it may preclude the development of a market because costs are also high and the number of interested consumers is small. If it is too low, it will not reduce risks significantly or motivate industry to improve safety.

Evaluating the costs and benefits of a certification intervention requires assessing the extent of market demand for the certified product and the resulting risk reduction. Useful information would include the consumers' willingness to pay for increased safety levels, particularly by consumers in high-risk groups or by institutions serving those consumers. Such willingness-to-pay estimates would indicate the potential value of higher safety and the potential market for a certified product. The social value of the certification program could then be measured by the reduced costs of illness resulting from market behavior or the willingness to pay for reduced risks. These could be compared to the costs to industry for providing a particular level of safety and the costs to Government agencies for certifying that safety level. Answers to these questions would indicate whether a market could develop for certification of a particular level of safety, and how far that market would go towards achieving public health goals.

Providing information may or may not represent the best approach to food safety, and must be designed and evaluated carefully. As Magat and Viscusi note, providing information is often attractive as a stopgap measure when risky behavior is likely to continue and the risks are small. However, some food safety risks are large. It may make economic sense to combine information with standards that exclude the lowest levels of safety from the market. Evaluating such a mixed approach is more complex, but it could be the basis for designing interventions that achieve better public health at the least cost.

Food Safety Indicators for Policy Analysis

The previous sections have outlined the kind of information needed to evaluate potential policies to reduce risks from foodborne illness. This section discusses some ideal indicators that might be developed to facilitate policy analysis. Indicators are constructed from time series data in order to interpret trends easily. One familiar economic

indicator is the consumer price index, which is constructed from price series data to provide an indicator of inflation. In the food safety area, many data series are in their infancy, so no indicators have been developed. A regular series of food safety indicators could provide information on the nature and extent of the food safety problem, and could be used to analyze the effects of food safety policies.

For example, a cost-of-illness index could be constructed from data on the incidence of illness and health care costs to indicate how the economic dimension of the food safety problem is changing over time. If broken down by pathogen, cost-of-illness indicators would show the relative economic importance of different pathogens. Other examples would be indicators showing the incidence of pathogens in farm animals, the adoption of management practices to control pathogens, and the costs of those practices. Such indicators could be used to analyze the costs of reducing pathogens at the farm level or the distribution of problems to be targeted for increased control or intervention. Data on the adoption of HACCP, the incidence of pathogens in products, and the costs associated with HACCP could be used to analyze the costs of reducing pathogens in meat products. Data on food intake and preparation methods for population subgroups could facilitate analysis of the distribution of benefits from reducing hazards.

As many food safety data series are in their infancy, it would be useful to outline potential indicators now in order to guide data collection efforts. There are four basic types of indicators: economic, proxy, physical, and distributional (Nelson and Miranowski, 1994). An economic indicator shows the severity of the food safety problem by measuring its cost to society. A proxy indicator shows the potential for a food safety problem; a physical indicator directly measures the existence of a food safety problem and its biological severity. Distributional indicators show how the risks and costs of risk reduction are distributed across different kinds of consumers and producers. Distribution is an additional dimension of any other indicator.

Table 2 shows some possible indicators and data sources. An example of a proxy indicator is the incidence of a pathogen in live animals or on slaughtered carcasses, which shows a potential food safety problem. The incidence of foodborne illness in the population from a particular pathogen would be a physical indicator that would show the existence of the problem. An economic indicator would be the costs of any illness caused by a particular pathogen. An example of a distributional indicator would be the incidence of illness in certain subpopulations. These examples demonstrate that proxy or physical indicators, and a scientific basis for linking

Table 2—Potential food safety indicators at various stages in the food chain

Type of indicator	Farm	Slaughter/ processing	Retailing	Consumer
Proxy	Nonadoption of control measures	Nonadoption of HACCP	Nonadoption of HACCP	Intake of risky foods; nonadoption of precautions
Physical	Pathogens in farm animals	Pathogens in meat products	Pathogens at point of sale	Incidence of illness
Economic	Cost of control measures	Cost of control measures	Cost of control measures	Benefits of reducing illness; willingness to pay for reduced risk; price premiums paid for safer products
Distributional	Geographic distribution of pathogens in farm animals	Incidence of pathogens by firm size	Incidence of pathogens by firm size	Incidence of illness by age
Potential data sources[1]	APHIS/FSIS	FSIS/industry	State and local agencies	ERS/ARS/ CDC/FDA

[1]APHIS = USDA Animal and Plant Health Inspection Service; FSIS = USDA Food Safety and Inspection Service; ERS = USDA Economic Research Service; ARS = USDA Agricultural Research Service; CDC = U.S. Department of Health and Human Services Centers for Disease Control and Prevention; and FDA = Food and Drug Administration.

the two, are often a prerequisite for building an economic indicator. The quality of the economic indicator (e.g., cost of illness) will be directly dependent on the quality of the physical data (e.g., incidence of illness).

There are several reasons why constructing these indicators would be difficult. First, some of the possible data sources listed are only potential sources. Many surveys are not regular and ongoing, do not cover the entire population of interest, or are not widely available for analysis. The National Animal Health Monitoring System conducted by the Animal and Plant Health Inspection Service only covers particular animals and focuses on veterinary issues rather than food safety issues. FSIS might be in a position to collect and report data from the slaughter/processing level, but it has not made such data public in the past. The Centers for Disease Control and Prevention data rely on the willingness of States, doctors, and individuals to report illness and their ability to identify a foodborne source of the illness. Therefore, these data do not adequately represent the extent of foodborne illness. Second, economic information often is not available, even when proxy or physical indicators are available. Economists need to work with the agencies that are generating data to encompass the economic dimension of physical indicators.

Conclusions

We have focused on laying out the range of possible alternatives and the data needs for evaluating alternative policies for managing food safety risks. We have not presumed that either incentive- or standard-based approaches are preferable, but we have discussed their pros and cons for addressing the complex issue of microbial foodborne pathogens. A standards-based approach needs to recognize the dual nature of HACCP as a process and a product standard, and its preventive nature as a potential benefit for regulatory efficiency. Providing information is often a preferred textbook solution, but given the changing structure of food markets, it may or may not address the underlying risks. Information approaches must be carefully designed to actually improve decision-making in the marketplace. Finally, regulatory approaches must be flexible, recognizing that there is an incomplete scientific basis for assessing the risks, producing safer products, and evaluating product safety.

The size and complexity of food safety problems caused by foodborne pathogens require careful consideration of the alternative policy responses and possibilities for managing the risks in the food supply. The failure of private markets to provide adequate information to con-

sumers due, in part, to the inherent variability of food products and processing, indicates a role for regulation and some Government involvement. What is required is the ability to monitor problems and changes in food safety risks, to identify priorities and alternatives for policy interventions, and to evaluate those alternatives within an economic framework. A coordinated effort is needed to identify and link data that will indicate the extent of the problems, to monitor changes (and improvement), and to provide the feedback that policymakers need to set priorities for directing scarce public and private resources to reducing the risk of foodborne disease.

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Integrating Data for Risk Management: Comments

Richard Williams

Food and Drug Administration, U.S. Department of Health and Human Services

The goal during this session is to discuss ways in which currently available data on human illness from foodborne disease can be integrated into cost-benefit analyses. Data on foodborne illness are prepared for the economist by a risk analyst. If they are to be useful, data must be in a form that can be used to calculate benefits. The major theme of these comments is that analyses done for microbial hazards must be quantitatively and qualitatively different from those done for chemical carcinogens. For example, unlike risk assessment for carcinogens, risk assessment for foodborne pathogens may present the full distribution of risk in terms of expected values.

Foodborne illness differs in a fundamental way from foodborne carcinogenic risk. For the latter, particularly in food colors, additives, and pesticides, the problem is to identify the compound that caused the illness. The solution is generally straightforward: to reduce or eliminate the amount of the compound in the diet via a tolerance. These risks are intentionally added and can be intentionally reduced.

The problem with foodborne pathogens is exactly the opposite. Foodborne disease is the result of sporadic, unpredictable events. The problem is not only to identify the microbial hazard that causes the illness, but also to identify a solution. In terms of data needs, it is less important to estimate the total number of cases of foodborne illnesses, now thought to be between 6 million and 33 million cases, than to find ways to reduce them.

Both risk assessment and cost-benefit analysis are performed to answer a risk management question. Because questions that are asked to control a chemical carcinogen differ qualitatively from those asked to control microbial hazards, these types of analyses differ. A preliminary list of similarities and differences is shown here.

Similarities:

- For most chemical and microbial hazards, there is an upward-sloping dose-response curve.

- For both microbial and chemical hazards, there is intraspecies variation in response to a hazard at a particular potency and level of exposure.

- It is not possible to achieve either zero carcinogenic risk or zero risk from either a microbial or a chemical hazard.

Differences:

- For chemicals, the beginning (preregulation) and reduced (postregulation) exposure may be known. For microbial hazards, both are a prediction that is based on an uncertain reporting statistic for an existing dose and a change in technology to predict the reduced dose.

- Better information for dose-response data is likely to come from epidemiology for microbial hazards (although animal studies may be useful), as opposed to animal data for chemicals.

- Again related to dose, chemicals are constant, intended, and predictable, whereas microbial hazards are unintended and sporadic—although they may be predictable based on existing outbreak patterns.

- Related to the last point, chemicals uniformly decrease in their exposure to humans from the point at which they enter the environment. Microbial pathogens increase and decrease throughout the stages of introduction until they are consumed.

- Although both chemicals and pathogens have high-risk subgroups, some are the same and some are different. Children are highly susceptible to both chemical and pathogen poisoning. However, people with liver disease and other immunocompromised conditions and the elderly are at high risk of pathogen poisoning, but not necessarily of chemical poisoning. In addition, where intraspecies variation may be a factor of 10 for chemicals, it is likely to be several orders of magnitude higher for pathogens.

- Chemical hazards are considered much more involuntary than microbial hazards. In the latter category, high-risk populations may be more easily identified, and all populations who are at risk can take simple steps to protect themselves from most of the hazards.

Although an oversimplification, there is generally one control strategy considered for chemicals—reducing the allowable amount of the carcinogen. For microbial reduction, there are many different strategies. First, because it is easier to identify the population at high risk from microbial hazards, self-protection by means of education is a more viable option. Other control options

include Hazard Analysis and Critical Control Point systems, irradiation, biotechnology (creating safe products), improved testing methods, improved identification and recall systems, and DNA fingerprinting. The last option will help create an actionable trail so that manufacturers and retailers will take more care to avoid lawsuits.

Finally, permit me two comments on the papers presented in this section. I believe that market failures must to be demonstrated on a case-by-case basis, because the existence *per se* of foodborne disease does not constitute a market failure (Jensen and Unnevehr). The optimal level of illness is always nonzero, because beyond some low risk, even well-informed consumers will not pay more for additional risk reduction. With respect to the paper by Roberts et al., I believe the general approach of probabilistic risk analysis will be the preferred approach, but I think caution should be exercised when attempting to turn quantitative variables into qualitative ones, because it is easy to create distributions that reverse priorities.

Integrating Data for Risk Management: Comments

Jason F. Shogren
University of Wyoming and Iowa State University

My comments on risk and the choice of safer food focus on three main points: (1) the inappropriate bifurcation between risk assessment and risk management; (2) the value of food safety, given the interdependence of private and collective risk reduction strategies; and (3) the impact of asymmetric information on the use of economic incentive systems in the regulation of food safety (for more specifics, see Shogren and Crocker, 1991).

First, the assessment and management of food safety risks are not separable activities, as implied by the current approach to risk analysis. Based on the recommendations of the National Academy of Sciences and the Environmental Protection Agency, risk analysis currently proceeds on the presumption that risk can and should be separated into two parts—risk assessment that quantifies a risk, and risk management that regulates the risk. The level of any given risk is quantified by the natural and biomedical sciences, and then the findings are made available to the lawyers, politicians, philosophers, and economists to be applied to the risk management process. Assessment occurs on one side, management on the other.

But just as one cannot do useful public-policy-based economics without the natural sciences, one cannot do useful public-policy-based science without the economics. Economic variables, such as relative prices and income, matter to risk assessment because people adapt to the risks they confront. Imagine all the resources that have been invested over the years to increase the likelihood that good things happen and that bad things do not. Individuals confronted with foodborne risks also invest resources in private protection to reduce the likelihood of suffering. How people make decisions about food safety risks varies among individuals and across situations with the relative incremental benefits and costs of their protection efforts, even though the properties of the foodborne pathogens that trigger these efforts may apply equally to everyone.

This realization has extreme impacts on the risk assessment of food safety. When people privately protect themselves, risk assessment and risk management become inseparable. Attempts to assess risk levels solely in terms of natural science will be misleading, costly private protection is a choice and may vary systematically in the observed risk-assessment data. The sources of the systematic variation are relative prices, incomes, and other economic parameters that influence any individual's protection decisions. For example, an individual may well perceive that private and collective efforts to increase food safety are substitutes. The individual's willingness to substitute one for the other is influenced by relative productivities and relative prices. A low or zero price for collective risk reduction will decrease private protection, thus increasing the level of observed risk. If the cost of collective reduction is high, however, the demand for private protection will increase, thereby reducing the observed risk levels.

We must explicitly address the simultaneous nature of how economic decisions affect food safety risks and how food safety risks affect economic decisions. Accurate risk assessment and effective risk management of food safety, given private and collective protection, requires a full accounting of a person's opportunities for input and output substitutions. A narrow or nonexistent description of these substitution opportunities implies that evaluations of food safety programs will be misdirected. The strict bifurcation must be reconsidered by incorporating the simultaneous system into food safety programs. We need to further explore how recent advances in technology will allow researchers and regulators to make more use of computers to integrate the interdependent physical and economic processes into a unified food safety system.

Second, current estimates of the costs of foodborne illness range from $4.8 billion to $23 billion. But cost-of-illness measures underestimate the true cost of unsafe food because individuals presumably would be willing to pay more than the actual costs incurred. These cost-of-illness measures, however, cannot be thought of as a consistent lower bound on the willingness to pay for safer food, given the interdependence of private and collective risk-reduction strategies. As was the case of risk analysis, both private and collective risk-reduction strategies must be considered in the benefit-cost analysis of safer food.

Researchers who use the concept of the value of a statistical life in benefit-cost analyses rarely acknowledge the existence of private risk-reduction mechanisms. The value of a statistical life is defined as the cost of an unidentified single death weighted by a probability of death that is uniform across individuals. But even if people have identical preferences, there are substantial differences in their ability and costs to alter a risk. The statistical-life approach fails to address the differences in

individual risks induced by private protection. An individual who has ready access to private protection will value collective mechanisms less. A complete assessment of this person's value for risk reduction requires considering their willingness to pay for private provision as well as for collective provision.

Not addressing the interdependence of private and collective risk-reduction strategies leads to the undervaluation of reduced risk and the misidentification of those who value food safety most highly. There are several reasons for undervaluation, all of which involve the inability to disentangle the relative values of private and collective contributions to risk reductions. If there is an exclusive focus on collective provision, the statistical-life approach will undervalue food safety as well. In addition, the statistical-life approach assumes that the value of risk reductions declines as risk decreases, although empirical evidence suggests that this value often increases. Rather than a lapse from rational economic behavior, the interdependence of private and collective risk reduction strategies can generate behavior that is consistent with increasing valuations of risk reductions. This challenges the standard view that those who are at greater risk and who have greater wealth must value a given food safety risk reduction more highly. It also implies that the undervaluations caused by a singular focus on collective risk reductions could increase with the degree of success gained by these collective efforts. As the effectiveness of successive collective provisions declines, the relative effectiveness, and therefore the value, of private provision increases.

The undervaluation problem can be resolved by assessing the individual's preference for alternative risk-reduction strategies. Psychologists and economists have observed that a person's valuation of a good can be influenced by alternative ways of representing the good. Evidence suggests that how a risk is reduced will affect the value an individual assigns to the protection of life. The risk-reduction strategy seems to matter. Because individuals can reduce the potential economic damages of a risk by employing private or collective protection either simultaneously or in sequence, understanding how these alternative strategies affect value is important for a better understanding of risk and the choice of safer food. By allowing the individual to reveal whether he or she would prefer to reduce risk privately or collectively or both, or by reducing the probability or severity or both, policymakers will have better measures of the value of safer food. Nonmarket valuation techniques, such as the contingent valuation method or experimental auction markets, can be used further to elicit preferences for safer food. But without first understanding how people prefer to reduce risk, program recommendations will be based on potentially precise but inaccurate, incomplete

information. This produces an unnecessarily restrictive policy environment, where a decisionmaker's prediction of the consequences of his programs may well be undone by individuals' actions.

Third, risks associated with food can be regulated either by the traditional command-and-control approaches, such as standards, or by economic incentive systems, such as taxes, subsidies, or marketable permits. In recent years, economic incentives have been promoted as cost-effective alternatives to command-and-control schemes, because the incentive systems allow more flexibility in the producers' decisions. The key to successfully implementing an economic incentive system for food safety is information—providing what everyone needs to know, finding out who knows what, and realizing the impossibility of knowing everything. No system of economic incentives, no matter how well it is supported by sophisticated technology, can be administered and enforced effectively if the people responsible for managing do not have adequate information on costs and actions.

For example, effective use of economic incentives for food safety requires information on: the benefits and costs of alternative risk-reduction strategies like Hazard Analysis and Critical Control Points (HACCP) and irradiation; the likely winners and losers; assessments of technological and institutional opportunities and constraints in the production of food and food safety; and substitution possibilities that would allow both policymakers and the regulated community to assess potential tradeoffs between more or less safe products and production processes. This information must be collected, stored, and disseminated to provide the knowledge base needed to implement economic incentives. Both regulators and producers need access to this information base.

Food safety regulation provides a significant challenge to the construction of an adequate information base. By definition, food safety implies numerous, diffuse sources of risk, thereby making it nearly impossible to perfectly monitor behavior and enforce any standard economic incentive system. As opposed to other risks, there is no convenient "end-of-pipe" treatment to provide common information for the design of an effective economic incentive system. Rather, the producer has private information on his or her costs and ability to reduce risk. This asymmetric information restricts the effective use of economic incentives, and requires more regulatory intervention in specifying the risk reduction strategy to be employed by the producer. New economic incentive systems need to be explicitly coupled with traditional command-and-control schemes.

The reason is that producers with private information about food safety risks can command "information rents"

by claiming they are harmed by the imposition of an economic incentive and must be compensated for their loss. If these claims are difficult to verify but are respected, the producer can extract extra rent from the regulator. Therefore, reducing information rents requires that economic incentives must sacrifice some efficiency of risk reduction. The food safety regulator must give up some of the efficiency that is gained from economic incentives to reduce the information rents that are associated with private knowledge on costs and the ability to reduce risk. Information rents will force a wedge between an optimal risk tax and the actual tax that reduced the information rent. This causes the regulator to set the risk-reduction level below the socially optimal level. By setting the tax lower than optimal, the cost advantage of the more efficient producers is diminished, thereby reducing their information rent. Reducing information rents requires a regulator to specify the mix of a firm's inputs to limit food safety hazards, thereby giving the firm little latitude to choose its own strategy to control hazards.

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Integrating Data for Risk Management: Comments

Skip Seward
McDonald's Corporation

This paper is a response to the questions and comments delivered in the preceding manuscripts regarding the characteristics and appropriateness of data pertaining to economic analyses of foodborne risks. First, it is important to understand that data affecting the current and future scientific, policy, and public health issues can be issue-specific or can be applicable to a range of fact-gathering and pathogen-control activities. The data also may be specific to a single industry, such as the beef industry, or applicable to a wide range of industry segments. Thus, defining the boundaries for the data being discussed is important for determining followup actions based on it.

The areas of common interest to the public and private sectors are numerous, and should drive the sharing of factual information to assist private industry in applying human and financial resources where there is the greatest opportunity to mitigate risks, and to assist those responsible for protecting public health in mandating effective policy requirements. Leveraging the combined resources for a particular risk reduction effort is the most cost-effective and rapid method for developing, implementing, and measuring a risk-reduction technique. This cooperative effort can be useful especially when the technology is not understood well or overtly supported by the public, such as with electronic pasteurization. Organizations such as the National Center for Food Safety and Technology in Summit, IL, or the National Food Processors Association in Washington, DC, can facilitate the information exchange. Obtaining the collective "best thoughts and data" will continue to be the biggest challenge for those interested in making this information transfer a reality.

Relative to marketing food safety, most persons in industry share the view that industry segments should not capitalize on food safety knowledge or expertise when customers are exposed to risks. When risk-reduction techniques are discovered, the methods must be shared with the entire industry to reduce the food safety risk for all consumers. Safety must be viewed by the industry as a basic customer expectation; as such, customers should not be thinking about food safety, nor be contemplating spending more for safe food.

As a specific example, consider the beef industry, which finds itself in the midst of an evaluation of risks inherent to beef. There is a sense of urgency about reducing the likelihood of foodborne illness from beef. Unfortunately, there is a knowledge gap between the desire for pathogen-free beef and the techniques that are available to reduce the risk most effectively. This knowledge gap affects the success of policies that are designed to control pathogens and reduce risks. In many cases, policies actually can increase risks, such as when contaminated carcasses are side-railed, only to sit at elevated temperatures that promote the growth of pathogens and increase the risk.

Risk-assessment data for the pathogens-in-beef concern, including proxy indicators (or the incidence of contamination), pathogen survival under various processes, and consumption data for susceptible and normal populations, are needed to better address the public health issues associated with ground beef consumption. Furthermore, to better understand the risk, the physical indicators (incidence of illness) and data on infectious doses are needed.

Except for pasteurization and retort equipment, data on the control or reduction of pathogens by food processing equipment, when that equipment is involved in a Critical Control Point (CCP), are generally unavailable. The data describing the risk of such equipment failing are necessary for accurate risk-assessment modeling. This is especially relevant since cooking has been identified as the CCP for ground beef at the restaurant level.

Risk-reduction strategies must be applied or the data-collection process is nothing more than a mental exercise. For example, the beef industry has incorporated numerous risk-reduction actions as a result of formal and informal risk assessments. Raw material suppliers receive training in Hazard Analysis Critical Control Point (HACCP) systems, and are requested to test raw materials for pathogens in order that the risk to the ground beef supply can be decreased. Beef carcass rinse-and-vacuum systems are tested by numerous slaughter operations and academic research institutions for their ability to reduce the risk of carcass contamination with pathogens. Now is the time to create policies that support making these types of proven interventions part of the required "best practices" for the slaughter industry.

There are steps that have been taken by the ground beef patty business, as well. Frozen beef patties present less risk of cross-contamination than fresh beef patties; the freezing process injures and kills certain pathogens. New grills, such as the clamshell grill, were introduced years

ago to improve the cooking of frozen beef patties. Hot holding and microwaving cooked products also reduce risks in the overall process. Risk assessments also have been important in defining the relative risks in food supplies, operations, and customer behavior. The human element remains a key factor for successful risk management.

From a policy standpoint, risk reduction in the beef industry requires more fact-based policy decisions. To date, policies on pathogen control have been inconsistent with data that define the hazards in the beef supply, especially in regard to where those hazards are introduced. Whereas end users of beef have regulatory consequences for risk reduction, the producers operate under a different set of standards. Policies must be fact-based as they relate to pathogen control, or they lose their significance and become barriers to those who are responsible for risk reduction.

The data used for establishing policies and procedures to reduce pathogens must be technically sound. There are two examples of this in the current efforts to reduce the risk of *Escherichia coli* O157:H7 infections from ground beef. Inspection testing traditionally used in the beef industry cannot ensure risk reduction and is generally not statistically significant; yet, such inspection testing is being proposed and practiced for risk reduction. Statistically based sampling can be very expensive, even with rapid tests. Furthermore, the relationships between pathogens and nonpathogens must be examined thoroughly if correlations are made relative to risk assessment and pathogen control.

A second example involves the policies on effective times and temperatures at which to cook beef patties to achieve safety. Regulatory times and temperatures that are based on laboratory testing can been improved by gaining a better understanding of the realities of cooking ground beef. The total heat lethality for any given process is an important consideration. Also important are factors relating to the methods and timing of temperature measurement, the realistic level of contamination likely to be present in ground beef, and the state of water in the ground beef at the time of cooking. These are important considerations for optimizing risk-reduction systems for thermal processing of ground beef patties.

Although HACCP systems are being proposed and mandated for beef processing plants, there are, in most instances, insufficient data to measure whether or not many CCP's actually control, or merely reduce, the hazards. This is especially true in the beef industry, where good manufacturing practices and CCP's often are mandated without clearly defining the risk reductions to be achieved. Specific examples range from hot water dips

for beef-slaughter equipment to hand-sanitizing stations for employees working in the fabrication rooms.

Gaining an understanding of the role of human vectors in disease transmission and propagation would be helpful in risk assessment and management. This is even more relevant as developing countries are integrated into globalization plans, since their infrastructure to support employees' personal hygiene outside the workplace may be minimal. This human-carrier state is not well documented or understood for many foodborne pathogens.

One of the primary difficulties facing those interested in measuring risks is the lack of criteria for substantiating foodborne illness. There are knowledge and verification gaps between alleged foodborne illnesses and proven foodborne illnesses. To expand databases without concurrent improvements in characterizing and validating illness adds little value to physical indicator data.

Data are needed that clearly express to what extent the customers' perceptions of a restaurant's concern for sanitation and hygiene affects the restaurant's success. Again, these principles are basic expectations of customers that must be met before there is any real excitement for them. However, as the drive-through business becomes a larger segment of the quick service restaurant business, for example, customers never have the opportunity to evaluate the physical environment of the food service facility, which typically is their only means of assessing sanitation and hygiene there.

A better understanding of the relationship between transient and resident microflora on the hands of workers, both in manufacturing and food service environments, would facilitate appropriate intervention strategies, such as using gloves, antimicrobial hand soaps, sanitizers, or barrier lotions. The real risk from human hands would be more clearly defined and placed in perspective relative to its importance in the transmission of foodborne illnesses. More definitive information on this subject would enable food service and health departments to focus their attention on the most effective interventions.

When people are the subject of study, policies on appropriate sampling and notification practices must be established to ensure that their rights are protected. Guidelines, such as those in the 1993 Food Code that request notifying health departments about persons who appear sick, are premature without more definitive human rights policies. Risks will be reduced successfully only with careful assessment of data from human subjects. The success of these surveys or followup investigations greatly depends upon the willingness of the individuals involved in the study. These persons need to understand their role in elucidating and establishing measures to

prevent foodborne illness. Anonymity during initial surveys could make gathering incident data easier because food service employees would not feel jeopardized.

As mentioned previously, the globalization of the food industry means that global work forces often are involved in the production and preparation of the world's food. Personal hygiene practices worldwide, and the environments in which the people live and work, more greatly affect the microbiological quality of the foods served throughout the world. Data on the incidence of potential foodborne pathogens and the transmission of the pathogens through people need to be global in nature to assist in risk assessments for global businesses and world health organizations.

Whether through traditional formal risk assessments, probabilistic scenario analyses, or fault tree analyses, there is a need for better understanding of the risks faced by food supply and service industries. The use of these techniques helps to clarify data gaps, set research priorities, and establish control measures. They also provide the basis for measuring the success of risk-reduction systems over time.

Integrating Data for Risk Management: Comments

Julie A. Caswell
University of Massachusetts at Amherst

Several major themes emerged from the questions and discussion following this session's presentations. The first theme focused on the structure and reliability of risk assessment and cost-benefit methodologies. Steven Crutchfield, the session moderator, commented on the direct corollaries between the risk assessment and valuation questions faced in the environmental and food safety areas. In both areas we do not have good information on the intermediate steps between a hazard and an array of possible final outcomes. He thought that probabilistic scenario analysis and fault trees showed promise in filling in these intermediate steps. Caroline Smith DeWaal said there was distrust of risk assessment and valuation methodologies because they were perceived as being misused, particularly in balancing the costs of illness against costs to industry for improved control.

Alwynelle Ahl responded that everyone must be included in the food assurance process so that risk assessment is believable and that communication is effective. Laurian Unnevehr said it is also important to build a clear explanation of data and assumptions used into analyses. Richard Williams noted that cost-benefit analysis is necessary because we do not want to chase after risk reductions that are not worth their costs. On consumers' role in risk assessment and valuation, Tanya Roberts commented that consumers need to be directly included in the setting of acceptable risk levels. This is particularly important because consumers are a direct link in the food chain and may introduce or mitigate foodborne pathogen risks by their actions.

A second theme of the discussion was to ask whether private markets for safer foods work effectively and are or could be a reasonable alternative to Government regulation. Several questioners asked Skip Seward about specific practices that McDonald's Corporation uses to assure food safety. Seward described steps that McDonald's has taken to introduce a Hazard Analysis Critical Control Point approach at retail; approaches it uses to specify its product quality requirements to suppliers; and its methods for setting standards. John Rhodes asked whether McDonald's is willing to pay premiums for safer foods and said suppliers are waiting for this. Seward responded that their analysis shows that the costs of the interventions they want for beef are inconsequential.

Michael Ollinger asked why, if kosher products demand a premium, there is not a "best practices" meat that could

also command a premium on the market? Jason Shogren responded that the market is imperfect now, so premium products may not be able to prove that they are premium and command a higher price. He noted that certification programs could make the market for food safety work better. Helen Jensen said that the important question may be what expectations consumers have. Consumers start with the expectation that food is safe and the market for safer foods may be targeted to special, higher risk populations. There is a potential for deception if food producers make safety claims when competing products are equally safe. Richard Williams said there appears to be a functioning market for food safety, as evidenced by consumers choosing cleaner looking establishments over less attractive ones.

Related to these themes, a third theme addressed the role of the media and public information in forming perceptions of the adequacy of risk assessment and food safety. Caroline Smith DeWaal posed this question, citing recent media reports on hypodermic needles in cans of soda and filming in meat packing plants. Richard Williams noted that many analysts in the risk-assessment community mistrust the media because they frequently do not get their coverage right. Melanie Scott responded that analysts need to speak to reporters in clear terms and understand the nature of what is news in order to communicate their findings effectively.

A fourth theme focused on how much money would be necessary to really do a good job of collecting data on foodborne pathogens to support policy and other decisions. Tanya Roberts estimated that the costs for a substantial subset of the information needed would be about $20 million. This cost seems minor, and it would be cost-effective to have better databases. She also said that some important demonstration projects could be done for substantially less money. Alwynelle Ahl pointed out that we are already spending a lot of money on food safety measures of unknown effectiveness. Better data could pay for itself by improving the effectiveness of food safety efforts.

The final theme of the discussion was the question of whose preferences for food safety count in Government regulations and private markets. For example, Ann Vandeman said that economists like to focus on consumers' willingness to pay for safer food products, but not so much on how income and income distribution affects willingness to pay. Whose preferences for food safety

and whose lives count? Jason Shogren responded that we do not know much about how demand for food safety changes as income changes (i.e., its income elasticity). Richard Williams said that executive orders require Federal agencies to look at distributional issues when evaluating new regulations, with food safety being viewed as a normal good (demand increases as income increases). Overall, the discussion in this session was concerned with the production of quality risk assessment and cost-benefit analyses that would support Government and private food safety assurance programs.

Section V

Policy Roundtable:
How Can Food Safety Data and Analysis Help in Program and Policy Design?

How Can Data and Analysis Help in Program and Policy Design?

James M. Hughes
Director
National Center for Infectious Diseases, USDHHS Centers for Disease Control and Prevention

David L. Swerdlow
Medical Epidemiologist
National Center for Infectious Diseases, USDHHS Centers for Disease Control and Prevention

In October 1992, an Institute of Medicine (IOM) committee cochaired by Joshua Lederberg and Robert Shope issued a report entitled "Emerging Infections: Microbial Threats to Health in the United States" (Lederberg et al., 1992). The report identified six major factors that result in the appearance of new and the reemergence of recognized infectious diseases: (1) changes in human demographics and behavior; (2) advances in technology and industry; (3) economic development and changes in land use; (4) increases in international travel and commerce; (5) microbial adaptation and change; and (6) breakdowns in public health measures. The committee expressed concerns about the complacency that has developed regarding control of infectious diseases in the United States, and emphasized the need for increased vigilance to detect new and reemerging infectious diseases so that rapid response can occur and control strategies can be implemented in a timely manner.

Each of the six factors identified by the IOM contributes to the emergence and re-emergence of foodborne diseases. Therefore, it is not surprising that there have been dramatic changes in the epidemiology of foodborne disease; e.g., new pathogens, new vehicles, and foodborne transmission of known pathogens. In recent years, foodborne diseases caused by *Escherichia coli* O157:H7, *Salmonella enteritidis*, and *Listeria* have emerged as important public health problems.

Epidemiologic data are critical to the development, implementation, and evaluation of public health programs. Epidemiologic techniques can provide data on the occurrence and determinants of disease. Laboratory data are critical in monitoring foodborne disease; use of appropriate techniques is essential. Sophisticated laboratory techniques can also be utilized to help recognize and address important public health questions. All of these data can then be shared with policymakers to set priorities, formulate policies, obtain and allocate resources, and plan, implement, monitor, and evaluate prevention and control programs.

With reference to foodborne disease, better data are needed on the incidence of and risk factors for disease, the proportion of disease caused by specific pathogens attributable to foodborne transmission, food consumption patterns, the cost of disease, and the effectiveness of control strategies. Resources are required to address these data needs. In a 1993 survey of State health departments, Berkelman et al. showed that 12 States had no full-time employees working on foodborne disease surveillance; therefore, the limitations of available data are not surprising. We urgently need improved surveillance to identify emerging foodborne diseases and to permit early recognition of and response to outbreaks of disease. We need improved diagnostic tests to identify pathogens in clinical specimens and in foods. In addition, with the shift to managed care and emphasis on cost control, there is likely to be decreased use of microbiology laboratories, compromising this valuable source of surveillance data.

Over half of the 15 recommendations in the IOM report were directed at the Centers for Disease Control and Prevention (CDC). In May 1994, the CDC released a plan for addressing emerging infectious disease threats to health (CDC, 1994). This plan was developed after

extensive consultation with numerous other agencies, organizations, and individual experts. Implementation of this plan will strengthen the public health infrastructure at the local, State, and Federal levels, and will contribute to strengthening global surveillance networks. The globalization of the food supply reinforces the need for an effective global surveillance network.

The plan contains four goals that address specific IOM recommendations in the context of a broad vision for revitalizing our Nation's ability to detect, contain, and most importantly, prevent the emerging infectious diseases that threaten populations both here and abroad. The first goal is to detect, promptly investigate, and monitor emerging pathogens, the diseases they cause, and the factors influencing their emergence. The second goal is to integrate laboratory science and epidemiology to address important research questions and provide data on the effectiveness of prevention measures in order to optimize public health practices. The third goal is to enhance the communication of prevention strategies to health care professionals and the public, and to ensure their prompt implementation. The fourth goal is to strengthen local, State, and Federal public health infrastructures to improve surveillance and implement prevention and control programs. The plan emphasizes the need to format new and to enhance existing partnerships among agencies, organizations, and industry. It also indicates the need to improve communication and collaboration between health care providers and public health officials. The surveillance and prevention of foodborne disease are important components of CDC's plan for addressing emerging infectious disease threats.

A second initiative that focuses on foodborne illnesses has been proposed to help determine the true incidence of foodborne diseases in the United States. The initiative is sponsored by CDC, the U.S. Department of Agriculture, and the Food and Drug Administration and will ascertain the yearly incidence of diarrheal illness caused by bacterial foodborne pathogens in selected population-based sites throughout the United States. In addition, the initiative will help determine the proportion of culture-confirmed cases of specific pathogens (initially *E. coli* O157:H7 and *Salmonella* serogroup B and D infections) that are attributable to eating specific meat, poultry, and produce items.

The study will consist of three parts: (1) active laboratory-based surveillance, (2) population-based surveys, and (3) nested case-control studies. Active laboratory-based surveillance will determine the number of laboratory-confirmed cases of bacterial foodborne pathogens and the number of stools submitted for culture that are identified from the study population. The population-based surveys will estimate the number of diarrheal episodes that occur in the study population each year, the proportion of persons with diarrhea who seek health care, the proportion of health care providers who obtain stool cultures, and the proportion of laboratories that culture stools for each bacterial foodborne pathogen. Information from active surveillance and the surveys will be combined to determine the incidence of diarrheal illness caused by each bacterial foodborne pathogen.

Nested case-control studies will determine the proportion of illness attributable to specific food items such as poultry, eggs, hamburgers, and fruits and vegetables. Persons identified during active laboratory-based surveillance will be used as the actual cases. Initially, only persons infected with selected pathogens such as *E. coli* O157:H7 and *Salmonella* serogroup B and D will be included, but future case-control studies could be performed that include persons infected with other pathogens.

Incidence rates of bacterial foodborne illness determined during the study will provide useful baseline rates to evaluate the effectiveness of new regulations in the food industry. Data from the study can also be used to evaluate the role of newly emerging foodborne pathogens in causing human illness.

Members of the IOM committee would probably not be surprised by the continued emergence of infectious diseases since 1992. As the health care system evolves, there is an urgent need to address the role of community-based public health functions to ensure a strengthened capacity to detect and respond rapidly and effectively to urgent microbial threats to health. Physicians, veterinarians, microbiologists, researchers, and public health professionals must work together and collaborate with colleagues in other Government agencies, industry, and the private sector to collect, analyze, and share the data required to design and evaluate the programs needed to meet the challenges posed by emerging infectious diseases.

It is of interest to consider what additional challenges the future may present. Drug resistance has emerged as a major public health problem; the importance of food in the transmission of drug-resistant organisms needs to be assessed. We can predict that we will discover new foodborne pathogens and that food may be identified as playing a role in the transmission of other microbial pathogens. The role of food in the transmission of *Helicobacter pylori*, the cause of peptic ulcer disease, needs to be assessed. Finally, it is critically important that we beware of becoming complacent. The impact of the North American Free Trade Agreement and the General Agreement on Tariffs and Trade, which will facilitate the international transportation of food, needs to be assessed.

As the authors of the IOM report concluded, "Pathogenic microbes can be resilient, dangerous foes. Although it is impossible to predict their individual emergence in time and place, we can be confident that new microbial diseases will emerge" (Lederberg et al., 1992).

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The Importance of Data in Pursuing a Science-Based Strategy for Protecting Public Health

Michael R. Taylor
Acting Under Secretary for Food Safety and Administrator
Food Safety and Inspection Service, U.S. Department of Agriculture

It is a pleasure to join you in your discussion on data needed to implement programs to reduce foodborne pathogens from farm to table. I applaud your efforts to bring together diverse groups that are interested and involved in food safety to discuss important issues related to reducing foodborne pathogens. It is through this type of cooperation and forging partnerships that we can begin to solve the important food safety problems we have before us.

I am certainly not here as a technical expert. I will leave the technical discussion of data and analysis to the experts in these areas.

Rather, I will provide you with a brief, philosophical overview of changes we are making in our food safety programs and how these changes will affect our need for, and use of, data. We are very aware that we need solid data to design, operate, and evaluate our food safety programs. We want to forge a partnership with academia, Government agencies, and industry to obtain the data we need to bring us closer to our food safety goals.

Program Changes

We are making very dramatic changes in the regulatory structure of our food safety programs. We have proposed a comprehensive regulation[1] that would mandate several important steps (FSIS, 1995). For instance, all plants that slaughter and process meat and poultry would be required to develop and implement Hazard Analysis and Critical Control Point (HACCP) systems. Under the proposal, we also would establish interim targets for pathogen reduction and mandate daily microbial testing in slaughter plants.

These and other changes would accomplish a number of important goals. They would build prevention into plant operations and focus inspection on prevention objectives. They would set public health-oriented interim targets for specific pathogens that all plants must meet. They would

also clarify that industry is accountable for producing safe food.

Establishing Health-Based Standards

The design, operation, and evaluation of these programs are going to require data. If we are going to establish health-based standards, we must know something about the pathogens present in food—what they are, where they are, and how they relate to disease occurrence.

Our microbiological baseline studies for various animal species have provided us with a starting point. We want to set interim targets for microbial pathogens based on the data that we have now. As we build a database, we can adjust these interim targets accordingly to meet our public health goals.

However, this is only an initial step toward articulating an acceptable level of food safety performance. The broader task of identifying levels of specific pathogens that pose a threat to public health is complex and requires us to work closely with Government and public health agencies, academia, industry, and consumer groups to develop the scientific basis for microbial risk assessment and health-based performance standards for pathogenic microorganisms.

Epidemiological methods will provide us with the data we need to develop health-based standards scientifically. That is why we have established a new Epidemiology and Emergency Response Program within the Food Safety and Inspection Service (FSIS). Its director is Dr. Glenn Morris, a physician, epidemiologist, and infectious disease expert.

Not only will epidemiological methods help us to set health-based standards but they will help us to measure whether the changes we make in our food safety programs are having an effect on overall foodborne disease rates. It is important that we have solid data to measure the impact of our programs so that we know if we are headed in the right direction. We cannot simply say our food supply is safe. We must be able to prove it through sound scientific data.

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[1] The agency's proposed regulations on Pathogen Reduction and Hazard Analysis and Critical Control Point systems were published in the *Federal Register*.

Government Role

The FSIS acknowledges its role in helping to collect needed data and is doing its part. Dr. Morris and his staff are working closely with the Centers for Disease Control and Prevention (CDC) and with the Food and Drug Administration to establish sentinel sites for collecting data on the incidence and etiology of foodborne disease. In a time-honored approach, they are also working with CDC and State health departments in outbreak investigations to identify possible breakdowns in current processing or processing control. A recent example of this is the investigation of the *Escherichia coli* O157:H7 outbreak associated with dry-cured salami products, which has raised questions about procedures in the dry-cured sausage industry.

Dr. Robert Buchanan, the new deputy administrator for Science and Technology, and his staff will continue to play a critical role in the collection of data on levels of specific pathogens in food and in developing microbial food safety systems for slaughter, processing, and distribution. Similarly, Dr. Bonnie Buntain, the director of our new Animal Production (Preharvest) Food Safety staff, will collect preharvest pathogen data and develop voluntary preventive controls at the animal production stage to reduce pathogens before animals reach federally inspected facilities.

While we are moving aggressively to collect data, we will never have all the answers we need to design perfect regulatory programs. We recognize that we lack perfect knowledge when it comes to controlling the risks posed by pathogenic microorganisms. We are still learning about infectious doses, modes of transmission, detection methodologies, process controls, and preharvest interventions. Our obligation to public health is to design the best programs we can based on the knowledge we have today. As we receive more information and data, we must be prepared to adjust our standards, procedures, and policies on food safety.

Government cannot be expected to provide all the data that are needed to design improved pathogen reduction systems from farm to table. Not only do we not have the resources, but we do not believe that should be our role.

Rather, we believe our role is to serve as a catalyst by helping to set the research agenda and encouraging cooperative research efforts among academia, Government, and industry. We also want to help convert knowledge that is obtained through research into concrete recommendations that can be implemented at various stages of the food production and distribution system. We cannot spend our time on an endless research and data-gathering effort. We must be clear about where we are going.

Conclusion

We look forward to working with you as we collect the data we need to effectively design, operate, and evaluate our food safety programs. New initiatives, such as HACCP and microbial testing, are only as good as the incoming data. This conference is an important first step in exploring our mutual needs for scientific data. We look forward to keeping communication lines open, sharing information, and working together to improve food safety.

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How Data and Analysis Can Help in Program and Policy Design

Lonnie J. King
Administrator
Animal and Plant Health Inspection Service, U.S. Department of Agriculture

In terms of public health, two factors affect problem solving and decisionmaking: the level of scientific and technical knowledge, and public value and opinion. Over time, public health has become a social as well as an individual responsibility. This change has made the issue of accountability especially problematic, and production agriculture has sometimes overlooked this factor in focusing only on the science involved in shaping policy. In retrospect, microbial food safety issues prior to *Salmonella enteritidis* and *Escherichia coli* O157:H7 were not driving forces in food production. Except for chemical residues, the farm-to-table continuum was largely disconnected, and the safety of our food supply was taken for granted. Thus, production agriculture is relatively new to this arena.

Food safety decisions are made daily in the absence of necessary data, in a policy environment where political agendas are inflamed, research is immature, resources are insufficient, and state-of-the-art research capability produces too few conclusive answers.

We have all suffered from decisions driven by crisis, hot issues, headlines, and organized interest groups that have lacked any comprehensive analysis. Tension continues between politics and professional expertise on these issues. As Eleanor Chelimsky stated in an article in *Science*, "The relation between researchers and decisionmakers remains one of inherently imperfect understanding, based as it is on the uneasy juxtaposition of different kinds of rationality and the dominance of politics over scientific logic in democratic societies."

Food safety needs to be viewed as an applied problem-solving activity. It operates under fiscal constraints, the need for more answers to many researchable questions, fragmentation of effort and opinion, and difficulty in mobilizing sustained efforts to solve problems, often due to the inherent conflict between the public value and today's level of scientific knowledge. However, policy development is the means by which problem identification, technical knowledge of possible solutions, and societal values converge to set an effective course of action. The convergence must fit reality.

We in the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS)

have considered ourselves to be strategic brokers for problem identification and resolution. Our programs and policies shift based on data and analysis. There are more problems than resources available; thus, new methods of collecting and analyzing data are especially critical, and we are left with difficult and complex problems to resolve. With fewer resources as a sure bet for USDA, problem identification is just as important as finding potential solutions. The Federal Government will have a changing role as partner, facilitator, and broker; we will be working with new coalitions and have a smaller yet more strategic role in actually implementing programs.

Partnering consists of building consensus and agreeing on outcomes. Our capacities for epidemiology, surveillance, and monitoring are evident, as are our strong analytical skills and our ability to focus and measure outcomes and impacts of programs and policies.

Another critical role in partnering is to serve as a clearinghouse for data from public and private research and field studies. Policy and program planners need access to central points where data have been distilled and analyzed. Agencies need to work together to establish "data hubs" and to ensure that information has maximum utility. In addition, we must try to ensure that data and information have a value-added effect. For example, as APHIS explores a facilitation role in quality assurance systems for food animal production, food safety data need to be synthesized into quality assurance studies, and vice versa.

We need a coordinated approach to research that looks at all links in the food safety chain in order to be able to formulate effective policy approaches to food safety. We need endpoint data and analysis to more accurately describe the magnitude and scope of human health impacts associated with specific foodborne pathogens. We need systems modeling and analysis to identify the most vulnerable links in the food chain. We need further data on production, processing, and distribution systems to pinpoint the most feasible and effective intervention points in the chain.

More narrowly in terms of preharvest, APHIS has identified the need for ecological and epidemiological studies to better describe and evaluate the dynamics of

transmission; the incidence, prevalence, and distribution of potential foodborne pathogens and risk factors in production systems; and management practices. These descriptive data must be collected and analyzed before intervention programs are designed. However, without proper problem identification and understanding, we may implement the wrong solutions. Most analytical tools fall into the "how-to" tool box (that is, economic value analysis and so forth)—tools designed to help do differently what is already being done. We must always be aware that "what-to-do" issues are really our central challenge. Means and ends should not be confused when we perform evaluations and seek options.

Food safety program design also requires accurate baseline data on human illness caused by foodborne pathogens, together with measurable indicators of progress and quantifiable goals so that we can accurately assess and revise our pilot interventions as better data and information become available. We also need to better understand the interactions between pathogens and systems of production and consumption in order to assure a logical fit among program objectives, assumptions, activities, and institutional vehicles.

APHIS has viewed its role in helping to provide food safety in terms of establishing a logic model for program and policy evaluation. With highly visible issues such as food safety, we look all too often to input and new activities as endpoints or indicators of success instead of focusing on outputs, outcomes, and eventual impacts. The old adage may apply, "What gets measured gets done." The cause–and-effect relationship between reducing or eliminating a potential human pathogen at the farm level, and reducing human illness, improving decisionmaking, and increasing consumer confidence in the United States, is a question to be addressed that offers a different reference for the successful conclusion of our efforts. In the prophetic words of Artemus Ward, "It ain't so much the things we don't know that get us in trouble. It's the things we know that ain't so."

In our discussion, we may also need to ask a different question: not, "What is safe?", but rather, "How much safety we can afford?" The answer to this question takes a different kind of analysis and perhaps a different set of data. It may be that science cannot define safety but can focus on the allocation of risk. The Hazard Analysis Critical Control Point approach to food safety seems to offer an appropriate framework for all areas of the food chain, including preharvest activities. The assessment and management of risk entail a pragmatic approach that should be sensitive to the reality of business while balancing societal concerns. However, the ability to set targets and levels of acceptable risk to the public is sticky and perhaps even cavalier. Ultimately, consumers decide how much safety they are willing to afford and how much risk they will accept. Willingness to pay and other indicators will provide information helpful in designing future programs and policies.

The role of Government programs in food safety may center on three core functions that will drive our data and analysis needs: (1) *assessment*—the collection, analysis, and dissemination of information on the occurrence and reduction of pathogens at all levels, such as descriptive data and onfarm HACCP models (a function that needs improved diagnostics to be performed well); (2) *policy development*—a science-based, strategic, and systematic plan for coupling problem identification with problem resolution while demonstrating an appreciation for the democratic and political environment in which the consensus-building process takes place; and (3) *assurance*—the matching of services and actions with goals and outcomes and the proper coordination of all actions. These functions are embedded in agreed-upon missions and steps for achievement, including regulations, organizations, linkages, capacities, and public education and involvement. These three functions of government are all in need of good data, analyses, and new methodologies.

Finally, as we review data and various analyses, we must always test our actions using realistic parameters. Do our programs and policies lead toward pragmatic, practical, doable, and cost-effective solutions? And are we making entities affected by our decisions part of the solution or plan? This will help to define success and to gain consensus on the outcomes and impacts of our actions at every step of the way along the food chain and from the various parties interested in food safety.

Data on Foodborne Pathogens: How Much, How Useful, How Costly?

Jean Kinsey
Professor of Applied Economics
University of Minnesota

There appears to be general agreement on "what we know" and "what we don't know" about the data available on foodborne pathogens. However, there is little agreement on what more we need to know.

Risks from foods of animal origin are a combination of many factors. In order to reduce the incidence of illness or death from foodborne pathogens, we need to ask, "How big is the problem?" and, "How can we learn about the complexity of the hazard?" The nature of the hazard is complex and includes understanding its nature, the amount of exposure, the dosage-response, and the cost of incidence. Many different types of information are required, including enormous amounts of microdata from individuals and numerous institutions (such as hospitals and testing agencies).

"How big is the problem?" Economists often measure size in terms of costs of illness or death, which include costs of medical treatment, lost income, and the value of lives lost. Another approach would be to measure the costs borne by suppliers to provide "safe" food. During the conference, there have been estimates that the costs of illness associated with food safety problems in meats and foods of animal origin are between $5 billion and $9.4 billion. However, even if the cost of collecting data needed to accurately identify food safety problems is $30 million, it is less than 0.6 percent of the costs of illness per year. Clearly there is an opportunity for investing in data collection to reduce the costs of foodborne disease.

Based on the evidence presented at the conference, the area of greatest need for data is linking acute disease with exposure to specific foodborne pathogens. Next is the need to expand this information for chronic disease symptoms. Such data are necessary to expand and refine cost estimates of both shortrun and longrun health problems and to obtain better measures of the benefits of decreasing incidence of illness or disability. Data on the benefits of decreasing particular illnesses allow comparisons with costs of controlling pathogens via HACCP or other mechanisms.

We need both macro- and microdata. By that, we mean data measuring aggregates versus data measuring individual processes and behaviors. The best science often requires *a lot* of microlevel data. This detail allows us to track individuals to learn about the temporal relationships of food intakes and illness. The "fault tree" analysis presented by Roberts, Ahl, and McDowell could be used to track a person who reports to a clinic and is ill. Another possibility is a longitudinal (panel) survey of a large number of individuals who would provide detailed records of food consumption, health behavior, and illness. These data might identify the need to follow up and monitor particular problems. Determining how much data and what kind of data is crucial. "Quality data" are critical—and costly.

Another approach is to collect macrodata. These are similar to the data we have now, although there is need for better reporting of incidence. Such data can provide "indicators" for detecting and monitoring change at the aggregate level. For example, such indicators might be used where there is a goal to decrease incidence of a foodborne illness by X percent. Then efforts can be concentrated on minimizing pathogen hazard and exposure to meet the target. It is important to note, however, that following this approach often leads to disregard for "who" gets ill.

The papers and discussion offered over the last 2 days have highlighted certain needs for research. First and foremost is the need for interdisciplinary research. This would include medical, epidemiological, animal science, economics, and public policy. For economists, there is a need to establish realistic and credible costs of bearing and of reducing foodborne illnesses. These should be comprehensive and include costs to: individuals (direct, lost work, lost household tasks); employers; and food sellers who experience loss or decreased sales and reputation. In addition, economists need to address the issues of estimating industry's and the public's willingness to pay for reducing a particular food hazard.

Both the interdisciplinary data and research needs, as well as the comprehensive nature of the data needed to address the problem, indicate the need for a centralized data collection and coordination effort. Federal and State agencies will need to work together. This includes the necessity for agencies to fund and coordinate efforts to collect data and to make them widely available to research and the public. Universities can provide the

science behind the generation of data, can analyze the data, and can serve as consultants to refine the data collection. Public agencies can help to facilitate interdisciplinary research. This might include setting a high priority on funding interdisciplinary teams of scientists, clinical specialists, and economists, for example. I have tried to highlight the nature of the problem, the complexity of the scientific question, and the role for research, especially for economists, to contribute to data collection efforts. A final question we need to address is: Do we want good, scientific data and analysis, or do we just want to decrease the observed incidence of illness? Answering this question may help to set priorities and guide public efforts to collect data to evaluate control options.

Foodborne Pathogens and Data Needs

Keith Collins
Director
Economic Analysis Staff, U.S. Department of Agriculture

My comments are inspired by the forces that have converged to generate this conference—principally, the growing interest in the control and effects of foodborne pathogens and the need to know more. I will focus on the following questions: Why do we need to know more? And what do we need to know?

My vantage point is from the Office of the Chief Economist at the U.S. Department of Agriculture (USDA). Our link to this issue stems from our role in the rulemaking process. The USDA is the fourth largest Federal department and the second largest in terms of rules issued each year. During the last 10 months, we issued about 600 rules reviewed by the Office of Management and Budge (OMB), of which about 200 were classified as either significant or economically significant. These rules require cost-benefit analysis, and our office must approve most of these analyses.

Two social trends over the past decade have affected our regulatory activities: rising disaffection with Federal regulation and the information age's demand for more data. These trends have led to procedures to try and ensure that regulations are justifiable. For example, the Administrative Procedure Act ensures involvement by the regulated public. In the early 1980's, OMB created the Office of Information and Regulatory Affairs to oversee Federal rulemaking. A series of Presidential Executive orders specified the process of cost-benefit analysis that must accompany rules that have an economic impact of at least $100 million—what are called "economically significant" rules. And in 1991, President Bush implemented a regulatory moratorium, adding to the regulatory analysis requirements. Over the past decade, analysis requirements have gotten tougher, and agencies have done a better job of meeting them.

These requirements are escalating again. In October 1994, the USDA became the first department with a statutory mandate to create an Office of Risk Assessment and Cost-Benefit Analysis requiring that a risk assessment be done for every rule that has an economic impact of $100 million or more and affects human health or safety or the environment. We are in the process of establishing that office and its operating procedures.

But before the ink is dry on our organizational paperwork, we are likely to have even newer marching orders.

One proposal for the first 100 days of the 104th Congress is the "Job Creation and Wage Enhancement Act," part of the Contract with America. This proposal would increase the analysis requirements for rules and would impose risk assessment on many more government rules directed at human health, safety, and the environment. I believe that a version of this legislation will be enacted, which could be significant for data and analysis needs in Federal rulemaking.

As an analyst, I welcome the growing public demand for analysis and information to support Federal regulation. But, as one who must sign off on these analyses, I am concerned about our capacity to do it right.

In order to do it right, the first maxim must be that "analysis precedes regulation." "Analysis first" must become part of a regulatory agency's culture. This sounds obvious, but analysis is often too aggregated to discriminate among program options. For this maxim to work, there must be sufficient data, robust analytical models, and skilled people in Federal agencies who know the data and can develop and apply the models and convey the analytical findings.

A second guiding principle should be "commensurability"—the more significant the rule, the more resources should be devoted to analysis. One view underlying this conference is that food safety risks and risk management options must be identified in an interdisciplinary way. The demand for analytical justification for Federal intervention is rising, whereas Federal resources are shrinking.

One solution to the needs/resources squeeze is to make the assets of organizations complementary. A multi-organizational effort is needed to build or systematically identify a database of food safety indicators that can be used to track progress in food safety and to provide response variables for measuring policy actions.

I would now like to turn to several of the requirements that Executive orders or law place on regulatory analysis and use these to discuss areas where more data and analysis are needed—where we need to help the professionals attending this conference.

- The first area of need is for *benefit estimates*. Executive Order (E.O.) 12866 requires that an attempt be made to quantitatively estimate the benefits of proposed action. Despite the underreporting of illnesses from foodborne pathogens, much has been done to measure the economic costs of these illnesses. But there is an immense gap in our knowledge about what happens on the farm or at the processing plant and the incidence of consumer illness. This is due in part to lack of pathogen baselines at different levels of production and distribution and uncertainty about the growth of pathogens in contaminated products and their probability of producing illness. Consequently, our cost-benefit analysis is quite limited; we simply are not able to show the dollar value of a reduction in illness due to a change in a specific process or performance standard.

  The E.O. requires us to assess less direct regulatory options for comparison, such as voluntary, incentive-based programs and consumer education programs. They are economically attractive in theory but have been made easy to dismiss because we do not know enough about potential participation by firms and whether education programs actually change consumer behavior.

  Another area of concern is the growing interest in contingent valuation. The U.S. Department of the Interior has recently proposed regulations to use contingent valuation in determining natural resource damages due to oilspills. Many say that our benefit estimates for food safety are too low because the value that consumers place on the avoidance of illness has not been measured. But how can this benefit be quantified without having the consumer truly face a choice among alternative goods and services with a real budget constraint? Much needs to be done in research to replicate the true market choice before this theory of consumer value can be used.

- A second area of need is the study of *indirect economic effects*. Here our food safety data must include addressing effects or changes in pathogen contamination on farm production, prices, and net returns. If processing costs rise, what is the impact on farm and consumer prices, production, and quantity demanded?

  Alternatively, what impact does an increase in food safety have on our food demand?

- A third area is defined by the Regulatory Flexibility Act, which requires us to evaluate the impact on small entities. What do we know about the health risks of small entities compared with average or large entities? For example, the impact on small firms was an important issue in USDA's rule on mandatory nutrition labeling. Evidence suggests that the small firms that account for about 10 percent of meat and poultry production often bear 30–50 percent of total industry control costs. That imbalance is often difficult for policy officials and politicians to accept. So we need to know more about small firms than just their share of industry output.

- A fourth area of concern relates to USDA's new risk assessment requiring *comparison of food safety risks with similar risks* regulated by USDA or other Federal agencies. Here again, we simply do not know much about comparing risk.

My interest in participating in this conference is to emphasize that growing public concern over the costs of foodborne pathogens and over tighter regulatory requirements are greatly increasing the need for more and better food safety data. Policy officials need the work of conference attendees to fulfill their public service obligations. This conference is an opportunity to forge interdisciplinary and organizational links to begin building a better food safety database.

With better data and analysis, more things are possible, including more cost-effective policy, expedited rulemaking, more timely interventions, an industry more receptive to regulation, greater public support, and a more persuasive position when requesting budget funds for both programs and research.

Summary and Critical Issues in Tracking Foodborne Pathogens

Tanya Roberts
Laurian Unnevehr
Economic Research Service, U.S. Department of Agriculture

Helen Jensen
Iowa State University

An Overview of Data Issues

In 1985, the National Research Council issued a report evaluating the scientific basis of the Nation's meat and poultry inspection program. The report focused on alternative strategies to assess and control risks from meat and poultry and to make food safety inspection more effective in protecting public health. Among the conclusions and recommendations was the need for a "rapid, timely, and flexible system to acquire, transfer, analyze, and make more widely available data related to inspection and to meatborne hazards." Data are needed to identify the nature and extent of the food safety problem arising from foodborne pathogens and to evaluate public and private management and control of microbial pathogens in meats and poultry.

In the last 10 years, there has been significant progress in developing scientific knowledge about foodborne disease, including improved tests to identify pathogens and advances in epidemiology for identifying control options. In some cases, traditional human illnesses have been newly linked to foodborne pathogens, and in other cases, new diseases and potential sources of contamination have been identified. This new scientific knowledge and increased public awareness of risks associated with pathogens in meat and poultry have led to calls for improved regulation—and information—on pathogenic microorganisms.

The policymakers at this conference emphasized the Federal Government's commitment to improving food safety. The Acting Under Secretary for Food Safety, Michael Taylor, said, "We want to forge a partnership with academia, Government agencies, and industry to obtain the data we need to bring us closer to our food safety goals." Hazard Analysis and Critical Control Points (HACCP) system regulations have been proposed to build prevention into plant operations and to focus inspection on prevention objectives (Taylor, 1995). The U.S. Department of Agriculture (USDA) also has a commitment to designing interventions using the best possible risk assessment and cost-benefit analysis (Collins, 1995).

Furthermore, recent international agreements make regulation of food product trade subject to science-based standards. Thus, interventions will increasingly be under scrutiny for their ability to reduce measurable risk in the most cost-effective manner. Lonnie King, Acting Administrator of the USDA Animal and Plant Health Inspection Service, suggests that we ask, "How much safety can we afford?" rather than "What is safe?" The need to evaluate alternative and existing interventions creates a demand for better data, and this conference was organized to assess data needs for evaluating control options.

In this conference, the papers and discussion have addressed the development of a system of data to protect public health and to manage the risks from unsafe meat and poultry. The following discussion highlights seven issues that were identified in conference presentations and discussion.

First, the speakers and questions from the audience highlighted *the lack of agreement on estimates of the number of cases of human illness associated with foodborne pathogens.* The estimated deaths range from 525 to 9,000 annually, and specific food links are difficult to document. An exciting announcement at this conference was a new initiative by the Food Safety and Inspection Service (FSIS), Centers for Disease Control and Prevention (CDC), and Food and Drug Administration (FDA) (Hughes and Swerdlow, 1995, discussed in detail later) to investigate cases of reported diarrheal disease at sentinel sites in order to identify causative pathogens.

Second, conference speakers all highlighted *the need for an integrated approach to the collection and analysis of data.* The nature of food production today is complex, and the potential for contamination exists at all stages of processing. Thus, data that will help to identify control options must encompass the entire food system. Furthermore, data on foodborne pathogens need to be linked across different stages of the food system in order to provide a better understanding of how pathogen sources relate to illness outcomes. The papers in the last session presented frameworks, such as fault tree analysis, for organizing information from throughout the food chain. Such linkage requires interdisciplinary and interagency cooperation. The conference represents an important first step towards such cooperation.

Third, there are key gaps in available data of all kinds, but *the data gap is greatest between the farm and the consumer.* Historically, data collection and reporting mechanisms have been developed to collect information regarding food consumption and incidence of illness at the consumer level and to collect information regarding management practices at the farm level. These historical mechanisms serve as the basis for current efforts to collect data regarding the incidence of foodborne illness or of pathogens among farm animals. However, there are no comparable mechanisms for collecting data at the processing and retailing levels of the food chain. This gap makes it difficult to link data on the incidence of pathogens among animals with data on specific illness outcomes.

Fourth, *how information is interpreted and reported will influence public perceptions and demand for safer food.* In this regard, food safety data present a good news/bad news dilemma. In the short run, there may be more "bad news" if more information documents the extent of human illness related to foodborne pathogens. Seward states that the food industry does not want consumers to think about safety when they eat out. But, as several speakers mentioned, "We can't manage what we can't measure." Furthermore, data collection can produce more "good news" about the success of control efforts. For example, listeriosis cases have declined, largely due to industry/Government control efforts (Tappero et al., 1995). Tensions over what information will be collected and how it will be reported need to be discussed and resolved.

A fifth and related issue is *the gap between public and private incentives to collect and report data.* Food safety information is a public good because it has value to the public generally, but it is too costly for each individual or firm to obtain independently (see Jensen and Unnevehr, 1995). The Government has a role in providing basic

information on the extent and origin of foodborne illnesses or in developing the basic science, such as pathogen-testing methodology, that facilitates information collection. While private industry has incentives to evaluate production processes and to develop new methods, both kinds of information are proprietary in nature. Industry may not have an incentive to share information that could be utilized to design public interventions (see Buchanan et al.).[1]

Sixth, *there needs to be consensus about how priorities will be set for data collection.* Priorities must be set because resources are limited and data are costly to collect, report, and analyze. Criteria are needed for deciding which foodborne pathogens are most important to control. Once these are identified, it becomes easier to prioritize data collection regarding control options. Because society has not reached consensus about who will bear the risks of foodborne illness and who will incur the costs of risk reduction, stakeholders may have different perspectives on which criteria are most important. Some proposed criteria for setting priorities are discussed below.

Seventh, *there are exciting new efforts underway and new opportunities to collect and utilize information.* As the demand for food safety information has increased, both public agencies and private industry are collecting new information. (A summary of publicly available data is found in Hamm, 1995). Both sectors are also developing new technologies—the public sector has invested in developing more rapid tests for pathogens, and industry has developed the clamshell cooker to assure better destruction of pathogens in hamburgers (see Seward, 1995). New methods of communication and analysis can reduce the cost of collecting, linking, or disseminating information. These opportunities may reduce the cost of developing an integrated data system.

In the remainder of this concluding paper, we first discuss how to set priorities for data collection, and then review highlights from the conference regarding key data gaps, new developments in data collection, and directions for the future.

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[1]Firms may have a *dis*incentive to share information because of a fear that data on pathogen contamination in a plant or in food samples could increase the possibility of a successful liability suit. However, firms with a good pathogen control program can persuasively argue that they are doing an effective job of monitoring and controlling pathogens.

Setting Priorities

Data and information are costly to gather. Furthermore, since pathogens differ in their entry points along the foodchain, the foods they are likely to contaminate, and their survival characteristics and responses to alternate control procedures, it is unlikely that one control technique will solve all foodborne disease problems (Council for Agricultural Science and Technology, 1994). Each pathogen must be examined individually to determine the most cost-effective strategies for control in the specific foods they contaminate. This need for pathogen-specific information increases the amount and cost of data needed to evaluate control options.

What criteria should be used to set priorities for collecting more data on foodborne pathogens? We assume that data are used to identify problems (for example, which foods are associated with which pathogens) and to estimate the benefits and costs of alternative solutions. It follows that data should first be collected for pathogens that pose the greatest problem, however defined. Roberts et al. (1995) advocate setting data collection priorities based on estimated economic costs to society of foodborne illness from specific pathogens. This collapses all acute and chronic illnesses and deaths into one number for the purpose of ranking priorities among pathogens and facilitates comparisons with the costs of alternative pathogen-reduction strategies.

Beyond setting priorities among pathogens, the general question we need to ask is, "What are the marginal benefits of better data on foodborne pathogens in being better able to evaluate alternative control procedures?" For example, using probabilistic scenario analysis, Griffin and Miller (1995) found that the bulk of the risk from the pine shoot beetle could be reduced by implementing one control strategy. The cost savings from not implementing the other 24 strategies, as planned by the State of Michigan, is a measure of the value of the information (see Roberts et al., 1995). Avoiding unnecessary or costly control options is one important reason to improve data collection.

If key gaps can be identified, putting more resources into generating data could be cost-effective. Since the human illness costs (medical costs and productivity losses) are currently several billion dollars (USDA FSIS, 1995) compared with Federal foodborne pathogen control programs that cost over $1 billion (GAO, 1992), increasing spending to identify more explicitly the nature of the foodborne disease and control options could be very cost effective. And new technologies making data readily accessible in a cost-effective manner are becoming more widespread. The following section discusses the key data gaps identified in the conference papers.

Key Food Safety Data Needs Identified

Conference papers identified a general paucity of data in the food safety area. While both industry and Government are undertaking new data collection efforts, remaining gaps are large. In summarizing the discussion, we define data needs to include research that would facilitate the collection of data through providing greater understanding of the nature of the food safety problem as well as specific information that could be collected through statistically valid surveys. For example, research to link foodborne illness to the existence of pathogens in farm animals is needed before surveys can be designed to monitor the incidence of pathogens and control measures at the farm level. These data and information needs fall into three broad categories: human health risk, the effectiveness of control options, and economic aspects of food safety policy options.

Foodborne Disease Incidence and Human Health Risk

CDC's foodborne disease outbreak reporting system was not designed to establish incidence of illness but rather to alert the U.S. Public Health Service to large outbreaks of foodborne disease where public intervention would be required.[2] Discussion during the conference focused on four major problems with the data on the incidence of foodborne disease. First, there is *uncertainty about the magnitude of acute illnesses*. Estimates of acute illnesses range from 6.5 million to 33 million annually (Buzby, 1995). Second, there is *uncertainty about the distribution of disease severity for acute illnesses, especially deaths, and the incidence and severity of chronic illnesses* resulting from exposure to foodborne pathogens (see Buzby (1995)). Third, although there is generic identification of high-risk individuals, *little is usually known about the specific characterization of the pathogen or pathogenic mechanism* (Council for Agriculture and Technology, 1994). Studies identifying specific foodborne associations with disease in high-risk populations are few (see Steahr (1995) for one example). Finally, *foodborne illness data are not linked to specific foods*. There is no

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[2]Sporadic cases of foodborne illness in people's homes are only incidentally included in foodborne disease reports if: more than two people become ill, food is recognized as the cause, the cases are reported to the State or local health department, or the health department does an investigation confirming that food is the source and reports it to the CDC. To estimate the actual incidence of human foodborne illness, the CDC has occasionally conducted special studies, the latest by Bennett et al. (1986) on the incidence of infectious disease. In 1994, a CDC working group estimated that infectious diarrheas are the second most common infectious disease in the United States (respiratory infections are first).

systematic way of estimating how much foodborne illness arises from particular food sources (see Ralston (1995)).

Data on Effectiveness of Control Options

The second major gap is information on the effectiveness of alternative control options. Hueston and Fedorka-Cray (1995) discuss two different ways to generate such information. One is through controlled experiments in a laboratory setting, which allow new control options to be evaluated. Another is through observational studies comparing microbial outcomes in different kinds of farms or firms, which permit the effect of existing management practices to be identified.

Laboratory experiments to control pathogens at specific levels of the production chain are rare. Their strength is clear identification of factors influencing pathogen control. But their findings may not apply in the less controlled environment of modern animal production and may not be cost-effective, since most of these studies lack information on economic feasibility.

Case-control studies are one kind of observational study where a pathogen-positive group is compared with a control group that is pathogen negative. Most case-control studies have been conducted to identify risk factors for human illness, and only a few have been conducted to identify risk factors related to hygiene and husbandry practices. One example is a Norwegian study that discovered that *Campylobacter* could be reduced by using chlorinated water in broiler houses (Kapperud et al., 1993). The strength of case-control studies is relatively rapid identification of economical and successful control techniques already used on some farms. Their weakness is a possible confounding of the results by unmeasured variables.

There are a few studies of the effectiveness of control options at the processing level, but they are scattered, and it is difficult to draw general implications from them for control strategies. Because many firms collect their own information, industry is a possible source of data on alternative control options. The adoption of HACCP may generate more data as firms monitor controls and keep records. Industry data at the processing level, however, depend on the unique product mix, sampling program, and reporting procedures characteristic of specific plants. Even if available, such data are hard to compare across firms. Furthermore, access to industry data is limited because of its proprietary nature and the legal liability potentially arising from pathogens in foods. As Bernard (1995), Kliebenstein (1995), and Buchanan et al. (1995) discussed, it may be possible to establish a clearinghouse for industry data that would provide confidentiality for firms and would standardize collection protocols.

Economics of Food Safety Policy Options

Economic data can provide information to evaluate relative costs and benefits of alternative policy options. The development of economic information regarding costs and benefits depends on sound scientific evidence of the kind outlined in the previous sections, linking pathogen contamination to consumer illness and control options to reduction of specific pathogens. Economic models depend on scientific information to describe systemwide impacts of control options.

Several speakers advocated using multidisciplinary teams of social and physical scientists to solve food safety problems. Kliebenstein (1995) emphasized the need to use a systems approach for identifying the widest possible array of solutions and estimating their impact. Buchanan et al. (1995) called for increased communication among disciplines. McDowell et al. (1995) discuss the interface among risk assessment, risk management, and economics.

To date, except for a few cost of illness and willingness to pay estimates, there are few data on the economic aspects of food safety. Data are needed that will allow comparison of costs of foodborne illness relative to the costs of control options. Cost of production data are available from a variety of sources for livestock production and processing. However, these data have not been linked to food safety outcomes. For example, industry census data can tell us the costs of slaughter and processing. But such data do not reveal whether plants are using HACCP or how costs and management techniques relate to the incidence of pathogens in products.

As economic data are developed, they would ideally signal the changes in costs to firms, benefits to consumers, and the payoffs from innovation in safety control. Economic indicators of food safety would allow comparison of costs and benefits of improving food safety in commonly denominated terms and would provide a signal of the relative willingness of the public to pay for additional food safety control (Jensen and Unnevehr, 1995). One example of such data might be indicators of the cost of illness, in aggregate and for specific pathogens. Other indicators might measure costs of control at different points in the production and distribution food chain. Indicators of potential risk from specific food sources would provide information with which to assess the distribution of risks to consumers, allowing education or regulatory control to address particular risks and problems of exposure.

Other economic information is needed on the costs of supplying various levels of food safety and the structure of costs (average and marginal) of using different

techniques to increase food safety. This includes information about the costs to firms of changing production practices, including the implementation of HACCP. The relative/marginal costs of control can be weighed against the marginal gains in food safety of the foods to obtain information on the cost-effectiveness of various strategies for food safety control. University, industry, and Government researchers can all contribute to the generation of this type of data. Estimates of consumer willingness to pay for safety, not generally known today, can provide measures of the degree to which costs of control will be met by consumers in paying higher prices.

New Developments in Data Collection

Several new or emerging efforts to collect data on food safety were discussed at the conference. These provide exciting opportunities to address the key data gaps identified above.

At the consumer level, Hughes and Swerdlow (1995) discussed the FSIS/CDC/FDA proposal to establish sentinel county surveillance for diseases with diarrheal symptoms. This surveillance would identify cases where people consult a physician, identify causative pathogens, and develop national incidence estimates. Even with a small sample size, estimates of foodborne deaths would be more credible than at present. Selected pathogens, such as *Salmonella* and *Escherichia coli* O157:H7, would be targeted to determine the specific proportion of illness attributable to specific food items. Depending on the level of funding, identification of food production and food consumption risk factors may be identified. Some data might also be generated on chronic sequelae. This surveillance system would help meet some of the critical needs for incidence data. What will clearly remain outside the study are those foodborne diseases that do not generate diarrheal symptoms.

At the slaughterhouse level, microbial baseline data are being collected in FSIS and will provide a picture of the incidence of major pathogens by animal species (USDA, 1995). At the farm level, the National Animal Health Monitoring System (NAHMS), discussed by Hueston and Fedorka-Cray (1995), is beginning to provide a picture of the incidence of pathogens in farm animals.

Some efforts are underway to facilitate building a database on industry practices. The standardization of test procedures and methods is an important component of building data systems to evaluate control options. Efforts to standardize the protocols include: the AOAC International's approval of pathogen tests for both FSIS and FDA, the Food Safety Consortium's work by

research microbiologists who could aid in standardizing data collection methods and perhaps serve as a clearinghouse for data collection, the National Advisory Committee on Microbiological Criteria for Foods' HACCP guidelines for production of various foods, the teaching of HACCP courses by several industry trade associations, and the Educational Testing Service tests on food handling procedures for restaurant employees.

The USDA Economic Research Service is undertaking an effort to construct food safety indicators from these data sources at all points in the food chain. Such indicators include updated and more comprehensive indices of the costs of foodborne illness. In constructing indicators for the food processing and farm sectors, existing cost data will be linked to microbial outcomes wherever possible.

New methods of communication make it possible to share and link data. Examples include the CDC's electronic communication for laboratory results and e-mail discussion groups/bulletin boards springing up on food safety topics.

Directions for the Future

Some research now underway will greatly help to conceptualize and improve our understanding of foodborne pathogens. This research will facilitate data collection and utilization of existing data. For example, fault tree analyses (or probabilistic scenario analyses) can utilize data to identify high-risk food production, marketing, and consumption practices—critical inputs for performing benefit/cost analyses of alternative control strategies to reduce foodborne pathogens. Predictive microbiological modeling shows the food processing circumstances that enable pathogenic bacteria to survive and multiply, which can aid in identifying control points. Identification of the infectious dose for pathogens for different population groups would aid in designing control programs for high-risk populations.

New technologies may facilitate the development of data systems and exchange of information between the private and public sectors and within the research community. Through coordinated efforts on database development, it may be possible to set up a data coordination system organized by links in the food chain. For example, it may be possible to link existing or emerging data sets. An interesting question is whether trends in human illnesses, identified by CDC, will mirror trends in FSIS baseline data for specific pathogens and NAHMS data on the incidence of pathogens in farm animals.

Rapid changes in the technologies of gathering and coordinating data will reduce the cost of information. Cheaper, easy to use, more rapid tests to identify pathogens will facilitate control, both because more testing is likely to be a part of the food safety control system (USDA, 1995) and because such information increases the range of control options. For example, farm-lot sampling in slaughterhouses might make possible increased control of specific products or introduction of followup and feedback to the farm source. Technological improvements in testing and tracking food products from farm to distribution are likely to change the nature, costs, and uses of data.

There was strong consensus at the conference that Government agencies, universities, industry, and consumers need to continue to work together in the area of food safety. Cooperation is needed to further identify the nature and extent of the food safety problem, to set priorities for data collection and research, and to integrate data collection and analysis along the food chain.

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Databases Used To Track Foodborne Pathogens from Farm to Table

Shannon Reid Hamm
Economic Research Service, U.S. Department of Agriculture

Introduction

The conference "Tracking Foodborne Pathogens from Farm to Table" brought together information on many of the national databases related to foodborne pathogens. The key tracking points in the food continuum where primary data exist include animal prevalence studies from the National Animal Health Monitoring System (NAHMS); individual dietary data that identify consumption habits involving high-risk foods and populations, from the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS) and the U.S. Department of Health and Human Service (USDHHS) National Center for Health Statistics (NCHS); and human illness data, primarily from the NCHS's Centers for Disease Control and Prevention (CDC).

Some of the conference papers described the data sets in detail, explaining their importance in identifying foodborne pathogens (Buzby, 1995). However, for most of the data sets, this paper provides more detailed information on the purpose of each survey, methodology, sample frame, descriptive variables, outcome variables for identifying foodborne pathogens, and contact person(s). Additional data sets available for use in tracking foodborne pathogens are also included. The data sets described later are summarized in table 1 by the type of data provided. However, this paper does not document all of the data sets available on foodborne pathogens and human illnesses.

Animal Prevalence Databases

National Animal Health Monitoring Systems (NAHMS)

The Veterinary Services, part of the USDA Animal and Plant Health Inspection Service (APHIS), responded to industry needs to increase information on endemic and noninfectious animal disease losses and their association with different production practices. NAHMS was created in 1983 to fulfill this mission with a set of six recurring objectives to meet information needs. In the first objective, end information users outlined their most important requirements. In the second objective, data to generate the information was collected after consulting with technical experts. The third objective was to analyze the collected data and generate information. Making the information, or summary data, available to users is the fourth objective, which is a continual process. The fifth was to evaluate the distribution, use, and impact of the supplied information to improve the process in subsequent cycles. The final objective was to direct this cyclical process in the most effective and efficient manner. The project started as pilot studies in seven States: California, Colorado, Georgia, Iowa, Michigan, Ohio, and Tennessee. Between 1983 and 1988, epidemiologic and economic data concerning cattle, sheep, swine, and poultry in breeding, feeding, and other types of operations were collected on an individual State basis. National surveys began in 1989 with the National Swine Survey. The following paragraphs discuss eight specific studies relating to foodborne pathogens that were carried out under the NAHMS. Contact person for general NAHMS information is Nina Rothenberger, NAHMS, USDA APHIS, at (970) 490–8000.

1. *National Swine Survey, NAHMS.* The study of swine health and productivity was a statistical sample of 1,661 reporting producers from 18 States conducted from December 1989 through January 1991. The objectives were to provide information on the production and health levels of the U.S. breeding swine herd and suggest factors that may affect sow health around farrowing and preweaning morbidity and mortality of piglets. Seven hundred and twelve producers agreed to continue providing data to State and Federal veterinary medical officers (VMO's). Each farm was visited four times over a 90- to 120-day period. Data collection instruments, such as diary cards, were implemented to collect prospective data on the farrowing to weaning stage of swine production for

Table 1—Foodborne pathogen databases available at the farm, consumption, and human-illness levels, and contact points

Farm level:
    National Animal Health Monitoring System (NAHMS)--
        National Swine Survey (970) 990–7820
        Swine Slaughter Surveillance Project (970) 490–7820
        National Dairy Heifer Evaluation Project (NDHEP) (970) 490–7827
        Escherichia coli O157:H7 in U.S. Dairy Calves (970) 490–7827
        Salmonella in Dairy Calves (970) 490–7827
        Cow/Calf Health and Productivity Audit (CHAPA) (970) 490–7855
        Cryptosporidium and *Giardia* in Beef Calves (970) 490–7855
        Cattle on Feed Evaluation (COFE) (970) 490–7855

Consumption level:
    U.S. Department of Agriculture (USDA) Agricultural Research Service--
        Continuing Survey of Food Intakes by Individuals (CSFII) (301) 734–8472
        Diet and Health Knowledge Survey (DHKS) (301) 734–8472
    USDA Economic Research Service and Agricultural Research Service--
        U.S. Food and Nutrition Supply Series (202) 501–7413
    U.S. Department of Health and Human Services (USDHHS) National Center for Health Statistics, Centers for Disease Control and Prevention--
        National Health and Nutrition Examination Survey (NHANES) (301) 436–7072
    Food and Drug Administration--
        Consumer Food Handling Practices and Awareness of Microbiological Hazards (202) 205–5349

Human-illness level:
    USDHHS National Center for Health Statistics, Centers for Disease Control and Prevention--
        National Health Interview Survey (NHIS) (301) 436–7089
        National Hospital Discharge Survey (NHDS) (301) 436–7125
        National Mortality Followback Survey (NMES) (301) 436–7464
        National Hospital Ambulatory Care Survey (NHAMCS) (301) 436–7132
        National Ambulatory Care Survey (NAMCS) (301) 436–7132
        National Medical Care Utilization and Expenditure Survey (NMCUES) (703) 487–4650
        Vital Statistics (301) 436–8954
        National Health and Nutrition Examination Survey I Epidemiologic Followup Study (301) 436–5975
        Behavioral Risk Factor Surveillance System (BRFSS) (404) 488–5304
        Waterborne Disease Outbreaks/Foodborne Disease Outbreaks (404) 639–2206
    Food and Drug Administration--
        Biotechnology Information for Food Safety (BIFS) (708) 728–4110
        World Wide Web Database linking the "Foodborne Pathogenic Micro-organisms and Natural Toxins Handbook" (202) 205–4682
    USDA--
        National Agricultural Library (NAL) Information Service on Foodborne Illness Prevention (301) 504–5719

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clinical signs associated with illness and death in sows, gilts, and preweaning piglets.

NAHMS Swine '95 collected data in June 1995 from producers in 16 of the largest swine-producing States. The survey will give a general overview of management and animal health on all sizes and phases of swine operations, much of which can be compared to results of NAHMS Swine '90. Data collected on the farm will target management and health in the grower/finisher phase of production. Presence of porcine respiratory and reproductive syndrome, *Salmonella*, and other swine pathogens will be assessed via fecal, serum, and feed samples collected on the farm. Fecal samples will also be tested for *Escherichia coli* O157:H7. The NAHMS Swine Commodity contact person is Dr. Eric Bush at (970) 490–7820.

2. *Swine Slaughter Surveillance Project, NAHMS.* NAHMS, in cooperation with the University of Minnesota, is supporting the development and evaluation of a model slaughter surveillance scheme. The model swine

slaughter check project in Minnesota was adapted from the Australian Pig Health Monitoring Scheme designed by Dr. Andrew Pointon of Australia. Producers wanting objective information about the disease status of their herds pay practicing veterinarians a fee to perform slaughter checks on a sample of their hogs. All inspectors are trained by the University of Minnesota to ensure uniform standards. The data are sent to the university and entered into a computer database from which reports are generated and immediately forwarded to the producer for consideration in herd health decisionmaking. The report details the prevalence of diseases and measures of severity for some lesions. A copy of the report is also sent to the consulting veterinarian. The computer program stores all data and generates summaries of industry disease status. The database contains information on approximately 6,000 slaughter hogs. Variables in the first database (PigMON) include an enzootic pneumonia, pleuritis, atrophic rhinitis, pleuropneumonia, and campylobacter. A second database allows disease rates to be estimated from the evaluation of a random sample of carcasses, thus giving a less biased assessment of the health status of Midwestern hogs at slaughter. The protocol was designed to spread the monitoring period equally over kill days and times. Seasonal biases were addressed by conducting inspections once each week for the 12 weeks of each season. The NAHMS Swine Commodity contact person is Dr. Eric Bush at (970) 490–7820.

3. *National Dairy Heifer Evaluation Project (NDHEP), NAHMS.* Data collection for the study began in 1991 and was completed in 1992. The NDHEP included 1,811 reporting farms in 28 States. These operations were randomly selected so that the results could not only be used to describe the participants but would be representative of herds of 30 cows or more in those 28 States. The herds represent 78 percent of the national dairy cow population. Descriptive herd management variables include colostrum management, recordkeeping, calf management, housing, contract raising, biosecurity measures, maternity hygiene, vaccination practices, use of nutritional supplements and feed additives, transfer of maternal immunity, *Cryptosporidium* prevalence, and milk replacer management. The NAHMS Dairy Commodity contact person is Dr. Scott Wells at (970) 490–7827.

4. **Escherichia coli** *O157:H7 in U.S. Dairy Calves, NAHMS.* The NDHEP was a 1-year study conducted through the NAHMS. In the 1,811 dairy operations, fecal samples were collected from approximately 7,000 preweaned calves from over 1,000 operations and tested for presence of *E. coli* O157:H7. Samples from a total of 25 calves from 19 farms (from 16 States) tested

positive for the organism, for an overall crude prevalence of 3.6 per 1,000 preweaned calves. To more clearly understand the relationship between the organism and the farm environment, a NAHMS followup study was conducted during 1993 and 1994. Objectives of the study were to describe shedding patterns in herds and to determine management factors associated with shedding. Producers from 50 negative NDHEP herds (control) and 14 positive NDHEP herds (case) participated. The study found changes in the presence of *E. coli* O157:H7: 11 of the 50 herds that originally tested negative tested positive, and 7 of the 14 that tested positive tested positive again. The NAHMS Dairy Commodity contact person is Dr. Scott Wells at (970) 490–7827.

5. **Salmonella** *in Dairy Calves, NAHMS.* The NDHEP conducted in 1991–92 determined *Salmonella* prevalence rates in dairy calves across the United States. Fecal samples were collected from 6,862 calves. An outcome of the study was data on the shedding rates of bacteria rather than cases of disease. Positive samples were found in 145 calves from all over the United States, but the highest prevalence was in the South. Primary sources of infection are identified. The NAHMS Dairy Commodity contact person is Dr. Scott Wells at (970) 490–7827.

6. *Cow/Calf Health and Productivity Audit (CHAPA), NAHMS.* A statistical sample of cow/calf producers was taken in a three-phase method to provide inferences about U.S. beef. The first phase was screening, during which enumerators from the National Agricultural Statistics Service (NASS) collected data from 3,397 cow/calf producers from September 29 to October 9, 1992, in all 48 coterminous States by computer-assisted telephone interview, asking questions about their management practices and the health of their animals. Results of this survey are available in "Part I: Beef Cow/Calf Herd Management Practices in the United States." The second phase was designed to collect data on nutritional and management practices from a subsample of producers with five or more beef cows who had 50 percent or more of their 1992 calf crop born between June 1 and June 30, 1992. Data was collected from 540 producers in 18 of the largest cow/calf-producing States from January 1 to February 28, 1993. Data for the third phase, collected between January 4 and February 28, 1993, was designed to provide information about health and health management from the 540 producers in part two of the survey. Each of the databases has a participant profile containing descriptive statistics from the subset of operations that completed the respective interviews and population estimates based on data collected, such as averages and proportions, that have been weighted to represent the cow/calf population. Results are available in "Part II: Nutritional & Reproductive Management Practices" and

"Part III: Beef Cow/Calf Health & Health Management."
Data for "Part IV: Beef Cow/Calf Breeding Management"
were collected from 523 producers continuing in the
program. VMO's conducted personal interviews with
producers from July 1–30, 1993. Data for "Part V:
Quality Assurance Profile" were collected from
495 producers who completed the entire program. VMO's
conducted personal interviews with producers from
January 1 to January 31, 1994. The NAHMS Beef
Commodity contact person is Dr. Dave Dargatz at
(970) 490–7855.

7. Cryptosporidium *and* Giardia *in Beef Calves,
NAHMS.* As part of the 1992–93 third-phase CHAPA
program, producers were offered the opportunity to
submit fecal samples from scouring beef calves that were
less than 3 months of age. Samples were tested for the
presence of *Cryptosporidium* and *Giardia*. In addition,
fecal pats from nonscouring calves less than 6 months of
age were similarly collected and evaluated. Producers
from a total of 69 operations submitted 391 samples from
diarrheic calves for *Cryptosporidium* and *Giardia* evalua-
tion. A total of 1,053 samples were submitted from
nondiarrheic calves from 141 operations. Outcome
variables include the percentage of calves that tested
positive for *Cryptosporidium* and/or *Giardia*, the relation-
ship of the positive test to the calves' age, and relation-
ship of positive test to presence or absence of diarrhea.
The NAHMS Beef Commodity contact person is
Dr. Dave Dargatz at (970) 490–7855.

8. *Cattle on Feed Evaluation (COFE), NAHMS.* From
August 1994 through December 1994, NAHMS, in
collaboration with NASS and the USDA ARS, conducted
a study of the feedlot industry. A stratified random
sample of feedlot operations from the 13 major cattle-
feeding States was contacted to collect data on health and
management (COFE). In phase one, 1,411 producers
provided data either by telephone or personal interview
on general management in their operations. Subsequently,
913 producers whose feedlots had a one-time capacity of
1,000 head or more provided data on health management
in their operations. The NAHMS Beef Commodity
contact person is Dr. Dave Dargatz at (970) 490–7855.

- E. coli *O157:H7 in U.S. Feedlots, NAHMS.* As part
  of COFE, 100 feedlots volunteered to have fecal
  samples collected from 4 pens of cattle to be evaluated
  for the presence of *E. coli* O157:H7. Data from this
  study are currently being analyzed. Reports will in-
  clude information on the presence of samples positive
  for the organism and an analysis of management
  factors (general and nutritional) related to prevalence.
  The NAHMS Beef Commodity contact person is
  Dr. Dave Dargatz at (970) 490–7855.

- Salmonella *spp. in U.S. Feedlots, NAHMS.* As part of
  COFE, 100 feedlots volunteered to have fecal samples
  collected from 2 pens of cattle to be evaluated for the
  presence of *Salmonella* spp. Data from this study are
  currently being analyzed. Reports will include informa-
  tion on the presence of samples positive for the
  organism and an analysis of management factors
  (general and nutritional) related to prevalence. The
  NAHMS Beef Commodity contact person is Dr. Dave
  Dargatz at (970) 490–7855.

Diet and Intake Databases

Continuing Survey of Food Intakes by Individuals (CSFII)

This survey, conducted by the USDA ARS, provides
information on U.S. diets and diets of population groups
of concern and how diets are changing over time. In
addition, it describes food consumption behavior and the
nutritional content of diets. The survey design is a
multistage, stratified area probability sample conducted in
1989, 1990, and 1991 (the 1989–90 data are the most
recent and complete available). The survey included the
collection of dietary recall and food record data for
multiple days. Detailed data are reported on the kinds and
amounts of foods eaten at home and away. Nutrients
ingested by individuals are derived from data developed
by the National Nutrient Data Bank. CSFII surveys were
conducted in 1985–86 and 1989–91; a new survey is
underway for 1994–97; and another is planned for
1998–2001. The contact point is Survey Systems staff,
Food Consumption Laboratory, USDA ARS, at
(301) 734–8472.

Diet and Health Knowledge Survey (DHKS)

This survey, conducted by the USDA ARS, provides
continuing information with which to assess relationships
between individuals' knowledge and attitudes about
dietary guidance, their food-choice decisions, and their
nutrient intakes. Some food safety questions were in-
cluded in the DHKS that generally relate to individual
perceptions about food safety. This survey is a followup
to CSFII. The 1989–91 survey design was a telephone
followup to the 1989–91 CSFII. The survey oversampled
low-income households. Combining the surveys allows
analysis of how the attitudes, knowledge, food handling,
and consumption patterns of households' primary meal
planners affect the households' food choices and dietary
status. Descriptive variables are the household income,
size, region, participation in Food Stamp and WIC
programs, sex, age, race, education, employment, and
pregnancy/lactation/nursing status. Outcome variables

include self-perceptions of relative intake levels, awareness of diet/health relationships, use of food labels, perceived importance of following dietary guidance for specific nutrients and food components, beliefs about food safety, and knowledge about food sources of nutrients. These variables can be linked to data on individuals' food and nutrient intakes from the CSFII. Contact point is the Survey Systems staff, Food Consumption Laboratory, USDA ARS, at (301) 734–8472.

U.S. Food and Nutrition Supply Series

The purpose of the series, conducted by the USDA Economic Research Service (ERS) and ARS, is to estimate levels of food and nutrients available for consumption in the U.S. food supply. Important uses of the series are to assess the potential of the food supply to meet nutritional needs (food security), to study the relationships between diet and disease over time, to estimate complete demand systems for price and income elasticities, and to facilitate management of Federal marketing, food assistance, nutrition education, and public health programs. The series design annually estimates amounts of major food commodities that disappear into the food distribution system at either the wholesale or retail level. Disappearance is derived by deducting data on exports, year-end inventories, and nonfood use from data on production, imports, and beginning inventories. Nutrient levels are derived by multiplying the per capita quantities of each food by the nutrient composition of the edible portion of the food. Outcome variables include per capita use for fresh and processed meats, dairy products, fruits and vegetables, and crops. The contact person is Judy Putnam, USDA ERS, at (202) 501–7413.

National Health and Nutrition Examination Survey (NHANES)

This survey, conducted by the CDC, assesses the health and nutritional status of the population and monitors changes over time. A major aim of the nutrition component is to provide data for monitoring nutrition, including tracking nutrition-related risk factors and estimating the prevalence of compromised nutritional status, and to provide relationships between nutrition and diet, nutritional status, and health. The survey design is a complex, multistage, stratified, probability cluster sample of households throughout the United States with two 3-year national samples conducted during 1988–94 (two national phases: 1988–91 and 1991–94). Several groups are oversampled: children, elderly persons, African-Americans, and Mexican-Americans. A dietary 24-hour recall and 1-month food frequency are used to obtain dietary data. Descriptive variables are gender, age, race, ethnicity, income, education, employment, health insurance

coverage, and material status. Outcome variables are numerous nutritional and health indicators, including food and nutrient intake; dietary practices; body measurements; hematological tests, including iron status; biochemical analyses of whole blood and serum; blood pressures; electrocardiograms; urine tests; bone densitometry; dental examinations; gallbladder ultrasonography; and cognitive and physical functioning. The contact person for the nutrition component is Ronette R. Briefel, Coordinator for Nutrition Monitoring and Related Research, at (301) 436–3473; the contact for the dietary component and Supplemental Nutrition Survey of Older Americans is the Health Statistician, Nutrition Statistics Branch, Division of Health Examination Statistics, CDC, at (301) 436–7072.

Consumer Food-Handling Practices and Awareness of Microbiological Hazards

This survey, conducted by the Food and Drug Administration (FDA), collected data about consumers' practices regarding food handling, storage, and shopping; about their knowledge of food safety principles and of microbiological hazards in foods and perceived sources of food contamination from chemicals and pesticides; about sources of information about food handling principles; and about consumers' foodborne illness experience. The survey was conducted between December 16, 1992, and February 7, 1993. The survey design is a national probability sample using a modified Waksberg random-digit-dialing procedure. A sample of telephone clusters of sufficient size to ensure that enough residential numbers would be identified for screening was randomly selected from the most recent Bellcore tape of U.S. area codes and telephone exchanges. A total of 1,620 interviews of English-speaking consumers were completed. Descriptive variables include age, geographic area, education, marital status, gender, race, and the number of household members 18 years or older. Outcome variables include general risk perception, awareness of foodborne microbial pathogens, meat/poultry/seafood handling practices and knowledge, consumers' consumption habit of high-risk foods, and foodborne illness experiences. The contact person is Sara Fein, Consumer Science Specialist, FDA, at (202) 205–5349.

Human Illness Databases

National Health Interview Survey (NHIS)

This basic health and demographic survey, conducted by the CDC, addresses major current health issues by annually collecting and analyzing data on the current population. The survey provides symptom data on

foodborne illnesses and an indication of the incidence and course of symptoms that can be linked up with more specific human illness data that identifies foodborne pathogens by International Classification of Diseases (ICD)–9 codes. National data on the incidence of acute conditions, episodes of persons injured, disability days, physician contacts, prevalence of chronic conditions, limitations of activity, hospitalizations, assessed health status, and other health-related topics are provided by the survey. The survey design follows a multistage probability design that has permitted a continuous weekly sampling of the civilian population of the United States since 1957. The current design began in 1985 and is expected to be used until 1995. Descriptive variables include demographic and socioeconomic variables such as age, sex, race, Hispanic origin, ethnicity, education, marital status, living arrangement, veteran status, income, employment status, occupation and industry, geographic region, and place of residence. Outcome variables include self-reported height and weight for persons 18 years of age and over, acute and chronic conditions, activity limitation, episodes of persons injured, restricted activity, self-assessed health, physician contacts, and hospitalization. The contact person is Gerry E. Hendershot, Chief, or Patricia F. Adams, Statistical Assistant, Illness and Disability Statistics Branch, Division of Health Interview Statistics, CDC, at (301) 436–7089.

National Hospital Discharge Survey (NHDS)

The NHDS, conducted by the CDC, provides data on patients discharged from non-Federal general and short-stay specialty hospitals in the United States and describes the nature, causative pathogen (ICD–9 codes), and treatment of illnesses within the hospital population. The survey has been conducted annually since 1965, and was redesigned in 1988 based on a three-stage probability sample of non-Federal short-stay hospitals within the national sample of primary sampling units (PSU's). Data are either abstracted directly from the factsheets of sampled hospitals' medical records or obtained from existing databases. Descriptive patient variables include age, sex, race, ethnicity, marital status, expected source of payment, length of stay, discharge status, diagnoses, and procedures received while in the hospital. Outcome variables include information on hospitalizations resulting from foodborne illnesses. The contact person is Robert Pokras, Chief, Hospital Care Statistics Branch, Division of Health Care Statistics, CDC, at (301) 436–7125.

National Mortality Followback Survey (NMFS)

The NMFS, conducted by the CDC, augments the information on characteristics of decedents by inquiring more fully into various aspects of concern to policymakers, health care providers and administrators, epidemiologists,

biomedical researchers, demographers, and the general public. Conducted from 1986 to 1988 and in 1993, the survey is based on a probability sample of all death certificates for adults over 25 years of age. Descriptive variables include cause of death, height, weight, medical history, medical care in last year of life, dietary patterns, lifestyle behaviors, and social and demographic characteristics. Outcome variables include the cause of death, which may be as specific as identifying deaths related to foodborne illness, health care utilization, other conditions, and functional limitations. The contact point is the Followback Survey Branch staff, Division of Vital Statistics, CDC, at (301) 436–7464.

National Hospital Ambulatory Medical Care Survey (NHAMCS)

This survey, conducted by the CDC, provides nationally representative data describing the utilization of hospital emergency and outpatient departments in the United States. The survey design is based on a multistage, stratified probability sample of non-Federal, short-stay hospitals selected within the sample clinics and emergency departments. Annual data collections are continuous throughout the year, with each hospital randomly assigned to a 4-week data reporting period that was initiated in 1992. Descriptive variables include demographic characteristics of the patient such as age, sex, ethnicity, and race. Outcome variables include patients' reasons for their visits (which may identify food poisoning), diagnoses (which may name a specific foodborne illness), diagnostic services, and medication therapy. For hospital outpatient department visits, nutrition-related information is collected. The contact person is James DeLozier, Chief, or Linda McCaig, Survey Statistician, Ambulatory Care Statistics Branch, Division of Health Care Statistics, CDC, at (301) 436–7132.

National Ambulatory Medical Care Survey (NAMCS)

The NAMCS, conducted by the CDC, provides a representative sample of all U.S. ambulatory office visits where patients are seen in an office setting by doctors of osteopathy and medical doctors other than those in government service and by pathologists, anesthesiologists, and radiologists. The survey includes only those physicians classified as "office-based patient care" by the American Osteopathic Association or American Medical Association. The survey contains randomly chosen regions or counties in the United States. The design uses a multistage probability sample design that involves identifying PSU's, identifying and sampling physician practices within these PSU's, and identifying a systematic random sample of patient visits within the selected physician practices. Physicians selected for the survey are randomly assigned a 7-day reporting period during which

time they maintain a list of all patients visiting their offices. Key variables include the treatment prescribed, the final disposition of the visit, and whether the patient had been seen previously by the physician. The wording of the patients' description of the principal reason and/or problem for the visit are collected alongside data on the physician's principal diagnosis. The data are available for individual years (1973, 1975–81, 1985, 1989–91). The number of records in the survey ranges from 29,102 to 71,594 per year. Descriptive variables include demographic characteristics of the patient, including age, sex, ethnicity, and race. Outcome variables include reasons for visit, diagnoses, diagnostic services, counseling services, and medication therapy. Nutrition-related information is collected. Contact person is James DeLozier, Chief, Ambulatory Care Statistics Branch, Division of Health Care Statistics, CDC, at (301) 436–7132.

National Medical Care Utilization and Expenditure Survey (NMCUES)

The NMCUES, cosponsored by the Health Care Financing Administration and the CDC, was designed to collect data about the U.S. civilian noninstitutionalized population during 1980. During the course of the survey, information was obtained on health, access to and use of medical services, associated charges and sources of payment, and health insurance coverage. The NMCUES consisted of three survey components. The national household component comprised 6,798 randomly selected households (17,123 persons) that were interviewed five times during 14 months from 1980 to 1981. The State Medicaid household component consisted of about 4,000 households selected from the Medicaid eligibility files in California, Michigan, New York, and Texas. Each household was interviewed five times during 14 months from 1980 to 1981. The administrative records component was used to obtain information on program eligibility and payments for medical care for Medicare and Medicaid recipients. The descriptive variables of interest include the number and types of disability days, emergency room visits, hospital outpatient department visits, medical provider visits, hospital stays, prescribed medicine, and other medical expenses. The medical provider visit file is helpful for quantifying the incidence and prevalence of foodborne illnesses that have ICD–9 codes. The NMCUES is available as public use data tapes from the National Technical Information Service at (703) 487–4650.

Vital Statistics

The purpose of the basic vital statistics program, conducted by the CDC, is to formulate and maintain a cooperative and coordinated vital records and vital statistics system with State-operated registration systems to produce national, State, and local data on births and deaths (including infant and fetal deaths and induced termination of pregnancy). U.S. vital statistics may be used for studying the incidence and prevalence of foodborne illness because vital statistics data use ICD–9 codes. The data have been published annually since 1915. Descriptive variables for births include the age, education, race, and Hispanic origin of mother and father; the marital status and nativity of mother; and the sex, birth order, and plurality of infant. Descriptive variables for deaths include the sex, age, education, marital status, race, and Hispanic origin of decedent; type and place of death; geographic place of death; occupation and industry of decedent; the decedent's residence; and whether an autopsy was performed. Descriptive variables for fetal deaths include the age, education, race, and Hispanic origin of mother and father; the marital status of mothers; the sex of the fetus; plurality; the live and total birth order; the place and date of delivery; and the geographical location. Outcome variables for births before 1989 include the infant's birth weight, gestational age, and Apgar score. Added in 1989 were data on the mother's weight gain during pregnancy, alcohol and tobacco use, and certain medical risk factors of pregnancy, such as anemia, diabetes, and hypertension; for the infant, new data included the presence of fetal alcohol syndrome, hyaline membrane disease, congenital anomalies, and anemia. Data on deaths include underlying and multiple causes of death that can identify foodborne illness by ICD–9 code. Data on fetal deaths include the period of gestation, the weight of the fetus, the month is which pregnancy prenatal care began, and the number of prenatal visits. Data that were also added in 1989 included the medical risk factors for this pregnancy; the complications of labor and delivery; the obstetrical procedures; the method of delivery; any congenital anomalies of the fetus; the mother's smoking, alcohol use, and weight gain during pregnancy; and attendants at delivery. The contact persons are: for Deaths, Harry Rosenberg, Chief, Mortality Statistics Branch, at (301) 436–8884; and for Births, Robert Heuser, Chief, Natality, Marriage, and Divorce Statistics Branch, at (301) 436–8954, Division of Vital Statistics, CDC.

National Health and Nutrition Examination Survey I Epidemiologic Followup Study (NHEFS)

The NCHS and National Institute on Aging conduct this study in collaboration with other national institutes of health and public health service agencies. The purpose of the survey was to investigate the relationships between clinical, nutritional, and behavioral factors assessed in the first NHANES (NHANES I) and the subsequent morbidity, mortality, and hospital utilization. The survey

periods covered 1982–84, 1986, 1987, and 1992. The population of interest was NHEFS cohorts between 25 and 74 years of age who completed a medical examination at NHANES I in 1971–75 (n = 14,407). The NHEFS is a series of followup surveys. The first wave of data collection was conducted for all members of the NHEFS cohort (n = 14,407) from 1982–84. The second wave, the 1986 NHEFS, was conducted for members of the NHEFS cohort who were 55–74 years of age at their baseline examination and   not known to be deceased at the 1982–84 NHEFS (n = 3,980). The third wave, the 1987 NHEFS, was conducted for the entire nondeceased NHEFS cohort (n = 11,750). The fourth wave was the 1992 NHEFS and included the entire nondeceased NHEFS cohort (n = 11,195). The survey design for all four waves involved tracing the cohort; conducting personal interviews with subjects or their proxies; measuring the pulse rates, weights, and blood pressures of surviving participants; collecting the hospital and nursing home records of overnight stays; and collecting the death certificates of decedents. The 1982–84 NHEFS interview included detailed questions concerning food frequency intake and vitamin supplementation. The 1992 survey used a 30-minute computer-assisted telephone interview instead of the interviews. The interviews did not include food frequency questions. Variables of interest included self-reports of selected physician-diagnosed medical conditions; histories of hospitalization and institutionalization; functional status; food frequency intake; vitamin supplementation; medication usage; smoking and alcoholic beverage consumption and history; physical activity levels; psychological status; physical measurements of pulse, blood pressure, and weight; and cause of death information about decedents. The contact person is Jennifer H. Madans, Ph.D., or Christine Cox, NCHS, at (301) 436–5975 or fax: (301) 436–8459.

Behavioral Risk Factor Surveillance System (BRFSS) Survey

The objectives of the BRFSS's, conducted by the CDC, are to provide State-specific estimates for the prevalence of high-risk behaviors, particularly those targeted in the USDHHS document "Healthy People 2000," such as overweight, smoking, and not using safety belts. In 1995, CDC began including a food handling and preparation module in the survey. The module will identify food handling and preparation practices, consumption of high-risk foods, and awareness of safe-handling instruction labels on meat. Six States, with 1,600 respondents each, administered the module. The sample, collected year-round, consists of a noninstitutionalized adult population (18 years or older) that was selected using a Waksberg random-digit-dialing telephone survey technique. Other than the module, the questions used are adopted from

NHANES and NHIS. The contact person is Paul Siegel at (404) 488–5296, or Craig Leutzinger at (404) 488–5304.

Waterborne Disease Outbreaks (1986–88)/Foodborne Disease Outbreaks (5-Year Summary, 1983–87)

The CDC has been actively involved in disease surveillance activities since the formulation of the Communicable Disease Center in 1946. The publication titled "CDC Surveillance Summaries" was initiated in 1982 after a survey was made of CDC staff and State epidemiologists. In 1985, the CDC Surveillance Coordination Group was formed with representatives from all Centers/Institute/Program Offices and from the Council of State and Territorial Epidemiologists. The Group was charged with developing and implementing a policy for CDC's public health surveillance activities. These activities, which are documented in regular reports, are directed toward achieving the following goals: conducting epidemiologic surveillance of all health events considered high priority; evaluating regularly all CDC surveillance activities; developing and evaluating improved methods for the collection, analysis, and dissemination of surveillance data; and maintaining and improving the expertise of CDC staff and constituents in the development, implementation, and evaluation of systems of public health surveillance. Data on the reported occurrence of notifiable diseases are derived from reports supplied by the State and territorial health departments and by CDC program activities. These data are published weekly in the "Morbidity and Mortality Weekly Report" ("MMWR"), and the final official numbers of cases are published in the annual "Summary of Notifiable Diseases." Complementary data are provided in "MMWR" surveillance summaries and recommendations and reports. Data reported in the weekly "MMWR" and the more detailed data reported by individual CDC programs are collected independently; therefore, some numbers may slightly vary because of the timing of reports or refinements in case definition. Caveats regarding the data include the following: some diseases that cause mild clinical illness and are infrequently associated with serious consequences are less likely to be reported than serious clinical illnesses with associated consequences; subclinical cases are seldom detected except in the course of epidemic investigations or special studies; the degree of completeness of reporting is influenced by the diagnostic facilities available, the control measures in effect, and the interests and priorities of State and local officials responsible for disease control and surveillance; and factors such as the introduction of new diagnostic tests and the discovery of new disease entities may cause changes in disease reporting independent of the true incidence of disease. The contact is the CDC at (404) 639–2206.

Additional Data Sets

Biotechnology Information for Food Safety (BIFS)

This database compiled by the FDA provides the literature access and technical data needed to use biotechnology and bioinformatics for food safety assessment and testing. The BIFS database currently contains a bibliographic database on food-related applications of genomic identification technology, a database of published genomic identification sequences for food-related microbes, and a database containing food-related toxin/gene sequences. A database containing sequence and structural information for food allergens is being constructed. The BIFS database is a unique access to information and analysis that would otherwise be difficult to obtain. The contact person is Steven M. Gendel, Chief, Biotechnology Studies Branch, FDA, at (708) 728–4110, or fax at (708) 728–4177.

World Wide Web Database

Through the World Wide Web server, the FDA's Center for Food Safety and Nutrition (CFSAN) has made available its most popular documents linking the "Foodborne Pathogenic Micro-organisms and Natural Toxins Handbook." The handbook contains basic facts on microorganisms and toxins, including their characteristics; habitat or source; associated foods; infective dose; and characteristic disease symptoms, complications, and recent outbreaks in susceptible populations. The information is supplemented through hypertext linkages to other computer systems containing food safety information. Examples of available supplemental information include the following: selected technical terms are linked to the National Library of Medicine's "Entrez" glossary system, selected chapters have hypertext links to recent articles from the CDC's "MMWR," selected chapters have hypertext links to the National Library of Medicine's "Entrez" abstracts of related scientific papers, selected chapters have hypertext links to the National Center for Biotechnology Information's GenBank of sequenced genetic loci of pathogens, and selected chapters have hypertext links to other CFSAN resources related to food safety. The Internet address is http://vm.cfsan.fda.gov/index.html; the contact person is Mark Walderhaug, CFSAN, FDA, at (202) 205–4682.

National Agricultural Library (NAL)

The USDA's NAL now provides an information service on foodborne illness prevention. The new service, called the Foodborne Illness Education Information Center, is designed for educators, trainers, and organizations developing education and training materials for food workers and consumers. The Center is a joint program of USDA's Food Safety and Inspection Service and the FDA. According to Cindy Roberts, coordinator of the Center, it was established by USDA and FDA in May 1994 as part of a national campaign to reduce the risk of foodborne illness and to increase knowledge of food-related risks at all stages of food handling and preparation, from production to consumption. "The Center's primary function is the development and maintenance of an educational database," Roberts said. "The database is a compilation of consumer and food worker education materials developed by universities, private companies, and government agencies."

Materials listed in the database include computer software educational research, audiovisuals, posters, games, and teaching guides—all for elementary and secondary school curricula. Also included are training materials for managers and workers at retail food markets and food service institutions. Roberts said that reports in the database are free and available by modem via the Internet from the gopher of NAL's Food and Nutrition Information Center. To access the database through the Internet, go to the NAS's World Wide Web server (http://nalusda.gov/fnic.html) or go to a public gopher site and make the following selections from the menus: All other gophers, Gopher Servers in the USA, Maryland, Food and Nutrition Information Center, USDA, USA/FDA Foodborne Illness Education Information Center. The Center can also be accessed through NAL's electronic bulletin board, ALF, and through PENpages International Food and Nutrition Database (IFAN). Floppy disk copies of the database are also available from the Center. NAL is one of three national libraries in the United States; the other two are the Library of Congress and the National Library of Medicine. Part of the USDA ARS, NAL is the largest agricultural library in the world. Additional information on the database and the Center are available by contacting Roberts at: USDA/FDA Foodborne Illness Education Information Center, c/o Food and Nutrition Information Center, National Agricultural Library, Beltsville, MD 20705–2351, at (301) 5041–5719, or fax at (301) 504–6409; the Internet address is croberts@nalusda.gov.

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Conference Participants*

Gary R. Acuff
Associate Professor, Food Microbiology
Texas A&M University
Department of Animal Science
College Station, TX 77843–2471
(409) 845–4425/Fax (409) 845–9354

Dr. Alwynelle Ahl
USDA/APHIS
4700 River Road, Unit 117
Riverdale, MD 20737
(301) 734–4391/Fax (301) 734–5899

Carlos Arbeyta, Jr.
Research Microbiologist
FDA
Seafood Product Research
22201 23rd Drive, SE
Bothell, WA 98041
(206) 483–4870/Fax (206) 483–4996

Ed Barron
Democratic Staff
Senate Agriculture Committee
328 Russell Building
Washington, DC 20510
(202) 224–2035

Dr. Parthapratim Basu
USDA/FSIS/S&T
300 12th Street, SW
Room 302, Cotton Annex
Washington, DC 20250
(202) 720–8623/Fax (202) 720–0582

Richard Belzer
Economist
Office of Management and Budget
NEOB, Room 10202
Washington, DC 20503
(202) 395–3088/Fax (202) 395–7285

Dr. George Beran
Department of Microbiology, Immunology and
 Preventive Medicine
Iowa State University
2134 Veterinary Medicine
Ames, IA 50011
(515) 294–7630/Fax (515) 294–8500

Dane Bernard
Vice President, Food Safety & Strategic Programs
National Food Processors Association
1401 New York Avenue, NW
Washington, DC 20005
(202) 639–5983/Fax (202) 639–5991

Doug Berndt, D.V.M.
Manager, Epidemiology Team
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Dr. Joe Blair
Executive Vice President
American Association of Food Hygiene
4910 Magdalene Court
Annandale, VA 22003
(703) 323–9327/Fax (703) 323–9327

Dr. James A. Boling
Associate Dean for Research
University of Kentucky
College of Agriculture
S–107 Agriculture Science Building North
Lexington, KY 40546–00910
(606) 257–3333/Fax (606) 323–3842

Colonel Dale Boyle
Staff Veterinarian
Defense Logistics Agency
8607 Conover Place
Alexandria, VA 22308
(703) 274–5823/Fax (703) 617–0851

Philip Brent
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW
Room 1108
Washington, DC 20005–4788
(202) 219–0756/Fax (202) 219–1252

Bob Brewer, D.V.M.
Staff Officer
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–7765/Fax (202) 720–5514

---

*Affiliations as of July 10, 1995

Dr. Joseph Bricker
Manager, Bacteriological Research
Research Intervet, Inc.
P.O. Box 318
Millsboro, DE 19966
(302) 934–8051/Fax (302) 934–8591

Robert L. Buchanan
Deputy Administrator
USDA/FSIS/S&T
300 12th Street, SW
Room 402
Washington, DC 20250
(202) 205–0495/Fax (202) 401–1760

Bonnie Buntain
Director, Animal Production Food Safety
USDA/FSIS
Room 0002, South Bldg.
14th and Independence Avenue, SW
Washington, DC 20250
(202) 690–2683/Fax (202) 720–8213

Dr. Jean C. Buzby
Agricultural Economist
University of Kentucky
c/o USDA/ERS
1301 New York Avenue, NW
Room 1108
Washington, DC 20005–4788
(202) 219–0905/Fax (202) 219–1252

Julie A. Caswell
Professor
University of Massachusetts
303 Draper
Amherst, MA 01003
(413) 545–5735/Fax (413) 545–5853

Dr. Harry Michael Chaddock
State Veterinarian
Michigan Department of Agriculture
P.O. Box 30017
Lansing, MI 48909
(517) 373–1077/Fax (517) 373–6015

Dr. Robert Charlebois
Chief, Processing Inspection Programs
Agriculture & AgriFood Canada
59 Camelot Drive
Nepean, Ontario
Canada K1A 0Y9
(613) 952–8000/Fax (613) 998–0958

Dr. Jhung Colby
Director of Microbiology Research
Perdue Farms Incorporated
P.O. Box 1537
Salisbury, MD 21802
(410) 543–3246/Fax (410) 543–3965

Dr. Peggy Coleman
USDA/FSIS/S&T
Room 302, Cotton Annex
300 12th Street, SW
Washington, DC 20250
(202) 720–0507/Fax (202) 720–0582

Keith Collins
Acting Chief Economist
USDA
Room 227–E, Jamie L. Whitten Federal Building
14th & Independence Avenue, SW
Washington, DC 20250

Joseph Cooper
Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW
Room 1108
Washington, DC 20005–4788
(202) 501–6970/Fax (202) 219–1252

Peter Cowen, D.V.M.
Associate Professor of Epidemiology/Public Health
College of Veterinary Medicine
North Carolina State University
4700 Hillsborough Street
Raleigh, NC 27606
(919) 829–4321/Fax (919) 829–4455

Stephen Crutchfield
Chief, Food Safety Branch
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW
Room 1108
Washington, DC 20005–4788
(202) 501–7415/Fax (202) 219–1252

Professor Patricia Curtis
North Carolina State University
Food Science Department, Box 7624
Raleigh, NC 27695
(919) 515–2956/Fax (919) 515–7124

Dr. Mark Dekich
Senior Director of Health Services
Perdue Farms Incorporated
P.O. Box 1537
Salisbury, MD 21802
(410) 543–3921/Fax (410) 543–3742

Caroline Smith DeWaal
Director of Food Safety
Center for Science in the Public Interest
1875 Connecticut Avenue, NW
Suite 300
Washington, DC 20009
(202) 332–9110/Fax (202) 265–4954

William H. Dubbert
Consultant
National Pork Producers Council
3412 Slade Run Drive
Falls Church, VA 22042
(703) 533–9238/Fax (703) 532–8621

Dr. Richard Duma
National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750
Bethesda, MD 20814
(301) 656–0003/Fax (301) 907–0878

Richard Duttan, D.V.M.
M.G. Waldbaum
105 Main Street
Wakefield, NE 68784
(402) 287–2211/Fax (402) 287–2660

Fay H. Dworkin, Ph.D.
Director, Division of Special Economic Studies
CPSC
Washington, DC 20207
(301) 504–0962/Fax (301) 504–0124

James T. Elfstrum
Manager, Regulatory Affairs
Rhone-Poulenc, Inc.
Prospect Plains Road
Cranbury, NJ 08512
(609) 860–4653/Fax (609) 860–0350

Kathleen Ellwood
Program Director
USDA/CSREES
Ag. Box 2242
Washington, DC 20250–2242
(202) 401–5178

Dr. Kit Farwell
EPA/HED/TOX
Room 823
1921 Jefferson Davis Highway
Arlington, VA 22022
(703) 305–6373/Fax (703) 305–5147

Paula J. Fedorka-Cray
Microbiologist, Lead Scientist
National Animal Disease Center
USDA/ARS
2300 Dayton Road
Ames, IA 50010
(515) 239–8672/Fax (515) 239–8458

Sara Fein
Consumer Science Specialist
FDA
CFSAN/OSAS/DMS/CSB
200 C Street, SW, HFS–727
Washington, DC 20204
(202) 205–5349/Fax (202) 260–0794

Joellen Feirtag
Assistant Professor
University of Minnesota
Department of Food Science
St. Paul, MN 55108
(612) 624–3629/Fax (612) 625–5272

Dr. Tom Feltmate
Associate Director, Epidemiology & Risk
 Assessment
Agriculture & AgriFood Canada
59 Camelot Drive
Nepean, Ontario
Canada K1A 0Y9
(613) 952–8000/Fax (613) 993–8959

Carol Tucker Foreman
Foreman & Heidepriem, Inc.
1100 New York Avenue, NW
Suite 1030
Washington, DC 20005
(202) 822–8060/Fax (202) 822–9088

Richard H. Forsythe
Distinguished Professor
Department of Poultry Science
University of Arkansas
Fayetteville, AR 72701
(501) 575–4773/Fax (501) 575–7294

Anthony E. Gallo
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1134
Washington, DC 20005–4788
(202) 219–1260/Fax (202) 219–1252

W.E. (Bing) Garthright
FDA
CFSAN
200 C Street, SW, HFS–708
Washington, DC 20204
(202) 205–5080/Fax (202) 260–0891

Steven Gendel
Chief, Biotechnical Studies Branch
FDA
6502 S. Archer
Summit, IL 60501
(708) 728–4110/Fax (708) 728–4177

John Goldberg
Science Fellow
House Agriculture Committee
1301A Longworth HOB
Washington, DC
(202) 225–4980/Fax (202) 225–4369

Lisa Grove
Policy Analyst
Office of Management and Budget
725 17th Street, NW, Room 10202
Washington, DC 20010
(202) 395–7340/Fax (202) 395–7285

Dr. Anne Haddix
CDC
EPO/PEA—Mailstop F53
1600 Clifton Road, NE
Atlanta, GA 30333
(404) 488–4945/Fax (404) 488–4953

Brenda Halbrook
Biological Scientist
USDA/FSIS
Cotton Annex Building, Room 411
300 12th Street, SW
Washington, DC 20250
(202) 205–0296/Fax (202) 401–1760

Mary Y. Hama
USDA/ARS
4700 River Road, Unit 83, Room 6C07
Riverdale, MD 20737
(301) 734–8485/Fax (301) 734–5496

Shannon Hamm
Data Coordinator
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1132
Washington, DC 20005–4788
(202) 219–0880/Fax (202) 219–0869

Charles Handy
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1134
Washington, DC 20005–4788
(202) 219–0859/Fax (202) 219–1252

Bill Hearl
Director
KPL/R&D
2 Cessna Court
Gaithersburg, MD 20879
(301) 948–7755/Fax (301) 948–5815

Erich Hemphill, D.V.M.
Staff Officer
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

David J. Henzler, D.V.M.
Poultry Epidemiologist
USDA/FSIS/APFS/POC
780 Eden Road
Lancaster, PA 17601
(717) 560–6960/Fax (717) 560–6965

Dr. Donna Hill
Regional Veterinary Services Manger
Perdue Farms Incorporated
P.O. Box 1537
Salisbury, MD 21802
(410) 543–3783/Fax (410) 543–3742

Jill Hollingsworth, D.V.M.
Deputy Director, EERP
USDA/FSIS
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

William D. Hueston, D.V.M.
Acting Director, Operational Support
USDA/APHIS/VS
4700 River Road, Unit 33
Riverdale, MD 20737
(301) 734–8093/Fax (301) 734–8818

Dr. James M. Hughes
Director, National Center for
 Infectious Diseases
CDC
1600 Clifton Road, M/S C12
Atlanta, GA 30333
(404) 639–3401/Fax (404) 639–3039

Michael Hume
Research Biologist
USDA/ARS
2881 FOB Road
College Station, TX 77807
(409) 260–9404

Leeanne Jackson
Consumer Safety Officer
Department of Health and Human Services
PHS/FDA/CFSAN/OFP/DHACCP
200 C Street, SW
Washington, DC 20204
(202) 205–4231

Lee-Ann Jaykus
Assistant Professor, Food Science Department
North Carolina State University
Box 7624
Raleigh, NC 27695
(919) 515–2971

Helen H. Jensen
Associate Professor
Iowa State University
568E Heady Hall
Ames, IA 50011
(515) 294–6253/Fax (515) 294–6336

Professor Frank T. Jones
North Carolina State University
P.O. Box 7608
Raleigh, NC 27695
Fax (919) 515–7070

Helen Jones-Fairnie
Curtin University
2113 130th Way
Rosemount, MN 55068–1637
(612) 423–7352/Fax (612) 423–7478

Sam Joseph
Professor of Microbiology
University of Maryland
Department of Microbiology
College Park, MD 20742
(301) 405–5452/Fax (301) 314–9487

Mark A. Kantor
Food and Nutrition Specialist
Dept. of Nutrition and Food Science
University of Maryland
3304 Marie Mount Hall
College Park, MD 20742–1018

Collette Schultz Kaster
Director Technical Services
Premium Standard Foods
P.O. Box 99
Milan, MO 63556
(816) 265–4061/Fax (816) 265–3089

Alison King
Veterinary Medical Officer
USDA/APHIS/VS
596 Eustis Street
St. Paul, MN 55104
(612) 646–4339

Dr. Lonnie J. King
Administrator
USDA/APHIS
Room 312–E, Jamie L. Whitten Federal Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 720–3668/Fax (202) 720–3054

Professor Jean Kinsey
University of Minnesota
317 COB, 1994 Buford Avenue
St. Paul, MN 55108
(612) 625–2744/Fax (612) 625–2729

Professor John Kirk
Auburn University
Large Animal Clinic
Auburn, AL 36849
(334) 884–6407/Fax (334) 844–6715

Les Kirkegaard, Sr.
KPL
2 Cessna Court
Gaithersburg, MD 20879
(301) 948–7755/Fax (301) 948–5815

Nicole Klein
USDA Ph.D. Fellow
R.R. 2, Box 199
White, SD 57276
(605) 629–3491

Professor James Kliebenstein
Department of Economics
Iowa State University
178B Heady Hall
Ames, IA 50011
(515) 294–7111/Fax (515) 294–4545

Heather Klinkhamer, Associate
Foreman & Heidepriem, Inc.
1100 New York Avenue, NW
Suite 1030
Washington, DC 20005
(202) 822–8060/Fax (202) 822–9088

Karl Klontz
Medical Officer
FDA
CFSAN/OSAS/DMS/EPIB
200 C Street, SW
Washington, DC 20204
(202) 205–5553/Fax (202) 260–0794

Ronald D. Knutson
Director, Agricultural & Food Policy Center
Texas A&M University
Agricultural and Food Policy Center
Department of Agricultural Economics
College Station, TX 77843
(409) 845–5913/Fax (919) 845–3141

Dr. David Kradel
Veterinary Epidemiologist
Pennsylvania Poultry Federation
500 N. Progress Avenue
Harrisburg, PA 17109
(717) 652–7530/Fax (717) 652–0230

Carol Kramer
Deputy Director for Research
Natural Resources and Environment Division
USDA/ERS
1301 New York Avenue, NW
Washington, DC 20005–4788
(202) 219–0453/Fax (202) 219–0029

Mr. David Kroeger
President, Mid-West Council, NJC
National Joint Council
310 West 20th Street
Fremont, NE 68025
(402) 721–7617/Fax (402) 721–7617

Fred Kuchler
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 219–0751/Fax (202) 219–1252

Dr. Betsey A. Kuhn
Acting Associate Director
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1132
Washington, DC 20005–4788
(202) 219–0880/Fax (202) 219–0869

Chinta Lamichhane
KPL
2 Cessna Court
Gaithersburg, MD 20879
(301) 948–7755/Fax (301) 948–5815

Bruce E. Langlois
Professor, Food Microbiology
University of Kentucky
Department of Animal Sciences
Lexington, KY 40546–0215
(606) 257–5881/Fax (606) 257–5318

George Laugelli
Program Management Analyst
USDA/FSIS/OA/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250–3700
(202) 205–0293/Fax (202) 720–5514

Dr. Beth Lautner
Vice President, Swine Health & Pork Safety
National Pork Producers Council
P.O. Box 10383
Des Moines, IA 50306
(515) 223–2600/Fax (515) 223–2646

Michael LeBlanc
Agency Survey and Data Manager
USDA/ERS
1301 New York Avenue, NW
Washington, DC 20005–4788
(202) 219–0334/Fax (202) 219–0146

Wendy A. Lepper
Blue Ribbon Task Force
National Livestock and Meat Board
900 Maple Road
Homewood, IL 60430
(708) 957–7878/Fax (708) 957–8405

Dr. Glenn Leslie
Veterinary Medical Officer/Public Health Officer
USDA/FSIS/OA/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250–3700
(202) 205–0293/Fax (202) 720–5514

Jordan Lin
Agricultural Economist
University of Florida
c/o USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 501–7405/Fax (202) 219–1252

James MacDonald
Senior Research Scientistt
Ohio State University
c/o USDA/ERS
1301 New York Avenue, NW, Room 1134
Washington, DC 20005–4788
(202) 501–6551/Fax (202) 219–1252

Jesse Majkowski, D.V.M.
Manager, Emergency Response Team
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Dr. Barry L. Marshall
Counsellor (Veterinary Services)
New Zealand Embassy
37 Observatory Circle, NW
Washington, DC 20008
(202) 328–4861/Fax (202) 332–4309

Sheila Martin
Senior Economist
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709
(919) 541–5847/Fax (919) 541–6683

Dr. Wilda H. Martinez
USDA/ARS
Room 1107A, Building 005
Beltsville, MD 20705
(301) 504–6275

Candace McCall, D.V.M.
Public Health Officer
USAF
HQ AF/SG, Bolling AFB
Washington, DC 22032–6188
(202) 767–1839/Fax (202) 404–8089

Steve McDermott
Staff Officer
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Robert McDowell
Senior Staff Economist
USDA/APHIS/PRAS
4700 River Road, Unit 117
Riverdale, MD 20737
(301) 734–5951/Fax (301) 734–5899

Scott McEwen
Associate Professor
University of Guelph
Department of Population Medicine
Guelph, Ontario
Canada NLG 2W1
(519) 824–1120/Fax (519) 763–3117

Deirdre McGlone
Human Services Planner
Mecklenburg County
Charlotte, NC 28203
(704) 336–4173/Fax (704) 336–6894

Dr. Edward L. Menning
Executive Vice President
National Association of Federal Veterinarians
1101 Vermont Avenue, NW, Suite 710
Washington, DC 20005
(202) 289–6334

Lawrence M. Miller
Senior Staff Veterinarian
USDA/APHIS/VS/NAHP
4700 River Road, Suite 204
Riverdale, MD 20737
(301) 734–7718/Fax (301) 734–7964

Dr. John A. Miranowski
Department Chair
Department of Economics
Iowa State University
260 Heady Hall
Ames, Iowa 50011
(515) 294–6740/Fax (515) 294–0221

Roberta A. Morales, D.V.M.
Agricultural Economist
North Carolina State University
Room 328, Patterson Hall
Raleigh, NC 27695–8109
(919) 515–4540/Fax (919) 515–6268

Dr. J. Glenn Morris, Jr.
Director, EERP
USDA/FSIS
Room 2168, South Building
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Morgan Morrow
Extension Swine Veterinarian
North Carolina State University
Box 7621
Raleigh, NC 27695–7621
(919) 515–4001/Fax (919) 515–6316

Joan Murray
Food Service Director
102 North George Mason Drive
Arlington, VA 22203
(703) 528–4564/Fax (703) 528–4564

Krishna Murthy
Staff Veterinarian
USDA/FSIS/APFSP
Room 0002, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 690–2683/Fax (202) 720–8213

Harry C. Mussman, D.V.M.
President & Chief Executive Officer
Food Technology Service, Inc.
5501 Seminary Road, #105–S
Falls Church, VA 22041
(703) 820–8454/Fax (703) 820–1814

Kenneth E. Nelson
Agricultural Economist
Commercial Agriculture Division
USDA/ERS
1301 New York Avenue, NW
Washington, DC 20005–4788
(202) 501–8554/Fax (202) 219–0356

Peggy Nunnery
Manager, Program Management Team
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Nfume (Jo) Nyamusika, D.V.M.
Agricultural Economist
University of Kentucky
326 Agricultural Engineering, #2
Lexington, KY 40546–0276
(606) 257–7272/Ext. 278/Fax (606) 323–1913

Joe O'Leary
Extension Specialist
University of Kentucky
203 Garrigus
Lexington, KY 40546
(606) 257–5882/Fax (606) 257–5318

Anita Okrend
Microbiologist
USDA/AMS/Science Division
Room 3517 South Building, P.O. Box 96456
Washington, DC 20090–6456
(202) 690–4025/Fax (202) 720–6496

Michael Ollinger
Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 219–0012/Fax (202) 219–1252

Dr. Delila Parham
Veterinary Medical Officer/Public Health Officer
USDA/FSIS/OA/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250–3700
(202) 205–0293/Fax (202) 720–5514

Mary Ann Parmley
Outreach Director
USDA/FSIS/ILA
Room 1180, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 690–0351/Fax (202) 720–4063

Gary Phillips
QA Director
McCarty Farms
P.O. Box 2579
Jackson, MS 39207
(601) 372–7441/Fax (601) 373–7272

Dr. Alan R. Post
USDA/AMS/Science Division
Room 3507 South Building, P.O. Box 96456
Washington, DC 20090–6456
(202) 720–3322/Fax (202) 720–6496

Pat Phibbs
Reporter, Health & Safety
Business Publications, Inc.
951 Pershing Drive
Silver Spring, MD 20910
(301) 587–6300/Fax (301) 585–9075

Bert Pritchett, D.V.M.
Staff Officer
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 205–0293/Fax (202) 720–5514

Dr. Sylvain Quessy
Bacteriologist
Agriculture—Canada
L.H.V.A. 3400 Casavant O.
St. Hyacinthe, Quebec J2S 8E3
(514) 773–7730/Fax (514) 773–8152

Katherine Ralston
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 501–6766/Fax (202) 219–1252

Edwin D. Reasoner
Vice President
Alexander & Alexander
1000 Walnut
Kansas City, MO 64199
(816) 391–1407/Fax (816) 391–1465

Tanya Roberts
Senior Economist
USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 219–0857/Fax (202) 219–1252

Robert A. Robinson
Professor
College of Veterinary Medicine
University of Minnesota
1365 Gortner Avenue
St. Paul, MN 55108
(612) 625–7260/Fax (612) 625–6241

Dr. John W. Rosevear
Technical Coordinator
Camas Diagnostic Co.
1313 Fifth Street SE, #219
Minneapolis, MN 55435
(612) 925–4218

Leon H. Russell, D.V.M.
Immediate Past President, AVMA
Professor, Texas A&M University
33 Linda Lane
College Station, TX 77845
(409) 845–3517/Fax (409) 847–8981

Chuck Sauer
Staff Officer
USDA/FSIS/EERP
Room 2168, South Building
14th & Independence Avenue, SW
Washington, DC 20250
(202) 720–3023/Fax (202) 720–5514

David Schardt
Associate Nutritionist
Nutrition Action—CSPI
1875 Connecticut Avenue, NW
Washington, DC 20009
(202) 332–9110/Ext. 326/Fax (202) 265–4954

Carole Schiffman
Director, Consumer Education
FDA
CFSAN
200 C Street, SW
Washington, DC 20204
(202) 205–5275/Fax (202) 401–3532

Wayne Schlosser
Analytical Epidemiologist
USDA/FSIS/APFS
555 S. Howes Street, Suite 200
Fort Collins, CO 80521
(970) 490–7846/Fax (970) 490-8099

Dr. Elizabeth Scott
98 Ridge Avenue
Newton, MA 02159
(617) 244–3070/Fax (617) 244–3070

Jenny Scott
Chief, Scientist Microbiology
National Food Processors Assoc.
1401 New York Avenue, NW
Washington, DC 20005
(202) 639–5985/Fax (202) 639–5991

Melanie Scott
Assistant Editor
Food Chemical News
1101 Pennsylvania Avenue, SE
Washington, DC 20003
(202) 544–1980/Fax (202) 546–3890

Dr. Skip Seward
Home Office Director
McDonald's Corporation
Kroc Drive
Oak Brook, IL 60521
(708) 575–6378/Fax (708) 575–6146

Phaedra Shaffer
Economic Analyst
Prevention Effectiveness Activity
CDC
1600 Clifton Road, MS F–53
Atlanta, GA 30333
(404) 488–4337/Fax (404) 488–4953

Jason Shogren
Stroock Distinguished Professor
Department of Economics and Finance
University of Wyoming
Laramie, WY 82071
(307) 766–5430/Fax (307) 766–5090

Bill Sischo
Assistant Professor
Pennsylvania State University
115 Henning
University Park, PA 16803
(814) 863–8526/Fax (814) 863–6140

Karla Springer
Senior Evaluator
U.S. GAO
1110 Vermont Avenue, NW, Suite 1000
Washington, DC 20548
(202) 512–9911/Fax (202) 512–9936

Carolyn Staples
Program Analyst
FDA
5600 Fishers Lane, Room 10–74
Rockville, MD 21043
(301) 443–0932/Fax (301) 443–4025

Dr. Karl N. Stauber
Under Secretary for Research, Education
 and Economics
USDA
14th & Independence Avenue, SW
Room 217–W, Jamie L. Whitten Federal Building
Washington, DC 20250

Professor Thomas E. Steahr
University of Connecticut
Department of Agricultural and Resource
 Economics
1376 Storrs Road, U–21
Storrs, CT 06269–4021
(203) 486–2838/Fax (203) 486–1932

Debra Street
Staff Fellow Epidemiologist
FDA
CFSAN/OSAS/DMS/EPIB
200 C Street, SW
Washington, DC 20204
(202) 205–5553/Fax (202) 260–0794

Dr. David Swerdlow
CDC
EDB/DBD/CID—Mailstop C09
1600 Clifton Road, NE
Atlanta, GA 30333
(404) 639–2206/Fax (404) 639–3970

Dr. Shaukad Syed
USDA/FSIS/S&T
300 12th Street, SW
Room 302, Cotton Annex
Washington, DC 20250
(202) 720–8623/Fax (202) 720–0582

Michael Taylor, J.D.
Acting Under Secretary for Food Safety and
 Administrator, FSIS
USDA
Room 331–E, Jamie L. Whitten Federal Building
14th and Independence Avenue, SW
Washington, DC 20250

Dr. Charles O. Thoen
Professor
Iowa State University
Department of Microbiology
Ames, IA 50010
(515) 294–7608/Fax (515) 294–8500

John Tilden
Medical Epidemiologist
CDC
1414 E. Washington Avenue #96
Madison, WI 53703
(608) 266–6761/Fax (608) 267–4853

Babgaleh Timbo
Medical Epidemiologist
FDA
CFSAN/OSAS/DMS/EPIB
200 C Street, SW
Washington, DC 20204
(202) 205–5914/Fax (202) 260–0794

Ewen Todd
Bureau of Microbial Hazards
Health Protection Branch/Health Canada
Banting Research Centre
Tunney's Pasture, Ottawa
Ontario K1A 0L2
(613) 957–0887/Fax (613) 941–0280

Professor William G. Tomek
Cornell University
254 Warren Hall
Ithaca, NY 14853
(607) 255–2189/Fax (607) 255–9984

Jodi Bunde Trenda
Washington State University
106 FSHN Department
Pullman, WA 99164
(509) 335–6498

Dr. Laurian Unnevehr
Acting Director
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1132
Washington, DC 20005–4788
(202) 219–0880/Fax (202) 219–0869

Ann Vandeman
Agricultural Economist
Food and Consumer Economics Division
USDA/ERS
1301 New York Avenue, NW, Room 1108
Washington, DC 20005–4788
(202) 219–0452/Fax (202) 219–1252

Donna U. Vogt
Analyst in Food Safety Policy
Congressional Research Service
Library of Congress
Washington, DC 20540–7490
(202) 707–7285/Fax (202) 707–7000

Dr. I. Kaye Wachsmuth
Deputy Director for Programs
FDA
200 C Street, SW
Washington, DC 20204
(202) 205–4057/Fax (202) 205–5025

Isabel Walls
Research Microbiologist
National Food Processors Association
1401 New York Avenue, NW
Washington, DC 20005
(202) 639–5974/Fax (202) 639–5991

Gary Weber
Associate Director, Animal Health
National Cattlemen's Association
1301 Pennsylvania Avenue, NW, Suite 300
Washington, DC 20004
(202) 347–0228/Fax (202) 638–0607

Joe C. Wells, D.V.M.
Executive Director
PETS—DC
2001 O Street, NW
Washington, DC 20036
(202) 234–7387/Fax (202) 857–0077

Dr. Irene Wesley
National Animal Disease Center
USDA/ARS
2300 Dayton Road
Ames, IA 50010
(515) 239–8291/Fax (515) 239–8458

Dennis R. White
Senior Technical Advisor
Elanco Animal Health
Lilly Corporate Center
Indianapolis, IN 46285
(317) 276–9785/Fax (317) 276–6116

Patricia White
Veterinary Medical Officer
USDA/FSIS/APFS/POC
780 Eden Road
Lancaster, PA 17601
(717) 560–6960

Richard C. Whiting
Lead Scientist, Microbial Food Safety
USDA/ARS
600 E. Mermaid Lane
Philadelphia, PA 19118
(215) 233–6437/Fax (215) 233–6581

Thomas G. Wilcox
Chief, Epidemiology Branch
FDA
CFSAN/OSAS/DMS/EPIB
200 C Street, SW, HFS–728
Washington, DC 20204
(202) 205–5652/Fax (202) 260–0794

Dr. Janet Collins Williams
Vice President, Science and Technical Affairs
American Meat Institute
P.O. Box 3556
Washington, DC 20007
(703) 841–2400/Fax (703) 527–0938

Dr. Richard A. Williams, Jr.
FDA
200 C Street, SW, HFS–727
Washington, DC 20204
(202) 401–6088/Fax (202) 260–0794

Cindy Wolf, D.V.M.
Small Ruminant Specialist
American Sheep Industry Association
225 VTH, 1365 Gortner Avenue
St. Paul, MN 55108
(612) 625–1780/Fax (612) 625–6241

Edward Zadjura
Assistant Director
U.S. GAO
1110 Vermont Avenue, NW, Suite 1000
Washington, DC 20548
(202) 512–9914/Fax (202) 512–9936

Dr. Robert G. Zimbelman
Executive Vice President
American Society of Animal Science
9650 Rockville Pike
Bethesda, MD 20814
(301) 571–1875/Fax (301) 571–1837